

US3412243 (Prod: New Horizons Clinical Research)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:34:16

All time stamps listed in this document are displayed in GMT

US3412243

Form: Participant Creation

Data signed: (b) (4) 16 Apr 2021 14:51:05

Generated On: 09 Jun 2021 17:34:16

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Participant ID

US3412243

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

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US3412243

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 05:02:10

Generated On: 09 Jun 2021 17:34:16

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 05:02:10

Generated On: 09 Jun 2021 17:34:16

Date of Birth (MMM yyyy)	(b) (6) 1954
Age	65
Age Units	YEARS
Age (Derived)	66
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	True
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 05:02:10

Generated On: 09 Jun 2021 17:34:16

Date of Informed Consent ( <i>dd MMM yyyy</i> )	14 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input checked="" type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 05:02:10

Generated On: 09 Jun 2021 17:34:16

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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) 13 Feb 2021 05:02:10

Generated On: 09 Jun 2021 17:34:16

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Were any significant conditions reported?

Yes ☒  
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 13 Feb 2021 05:02:10

Generated On: 09 Jun 2021 17:34:16

Condition	PERENNIAL ALLERGIC RHINITIS
Start date (dd MMM yyyy)	UN UNK 1960
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 1960
Start Year (derived)	1960
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 13 Feb 2021 05:02:10

Generated On: 09 Jun 2021 17:34:16

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 13 Feb 2021 05:02:10

Generated On: 09 Jun 2021 17:34:16

Condition	ASTHMA
Start date (dd MMM yyyy)	UN UNK 1962
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 1962
Start Year (derived)	1962
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 13 Feb 2021 05:02:10

Generated On: 09 Jun 2021 17:34:16

Condition	SLEEP APNEA
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 (5)

Data signed: (b) (4) 13 Feb 2021 05:02:10

Generated On: 09 Jun 2021 17:34:16

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 13 Feb 2021 05:02:10

Generated On: 09 Jun 2021 17:34:16

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2013
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 2013
Start Year (derived)	2013
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 13 Feb 2021 05:02:10

Generated On: 09 Jun 2021 17:34:16

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 13 Feb 2021 05:02:10

Generated On: 09 Jun 2021 17:34:16

Condition	OSTEOARTHRITIS: ELBOWS, KNEES
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 13 Feb 2021 05:02:10

Generated On: 09 Jun 2021 17:34:16

Condition	DIABETES TYPE 2
Start date (dd MMM yyyy)	UN UNK 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 13 Feb 2021 05:02:10

Generated On: 09 Jun 2021 17:34:16

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 05:02:10

Generated On: 09 Jun 2021 17:34:16

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	14 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	11:10 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 11:10
Height ( <i>xxx.x</i> )	145.5 cm
Weight ( <i>xxx.x</i> )	84.5 kg
BMI ( <i>xxx.x</i> )	39.91450 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 05:02:10

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 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) 13 Feb 2021 05:02:10

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Date of assessment (*dd MMM yyyy*) 14 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) 13 Feb 2021 05:02:10

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☒ No ☐

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**Specify**

LIVES IN HIGH RISK COUNTY

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

**No Risk Identified** False

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 05:02:10

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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)	True
<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)	False
<b>Other</b>	False
<b>Specify</b>	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 05:02:10

Generated On: 09 Jun 2021 17:34:16

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

Visit date (dd MMM yyyy)	14 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) 13 Feb 2021 05:02:10

Generated On: 09 Jun 2021 17:34:16

What was the date of randomization? (dd MMM yyyy) 14 AUG 2020

What was the participant's randomization number? 186359

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) 13 Feb 2021 05:02:10

Generated On: 09 Jun 2021 17:34:16

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) 13 Feb 2021 05:02:10

Generated On: 09 Jun 2021 17:34:16

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)	14 AUG 2020
Time of assessment (00:00-23:59)	11:10 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 11:10
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3412243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 05:02:10

Generated On: 09 Jun 2021 17:34:16

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 AUG 2020
Time of assessment (00:00-23:59)	12:36 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 12:36
Temperature (xxx.x)	96.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 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) 13 Feb 2021 05:02:10

Generated On: 09 Jun 2021 17:34:16

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) 13 Feb 2021 05:02:10

Generated On: 09 Jun 2021 17:34:16

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) 14 AUG 2020

What was the treatment time? (00:00-23:59) 12:05 (24 HR)

Treatment Date and Time (derived) 14 AUG 2020 12:05

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) 13 Feb 2021 05:02:10

Generated On: 09 Jun 2021 17:34:16

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

Collection date (dd MMM yyyy)	14 AUG 2020
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Collection time (00:00-23:59)	11:40 (24 HR)
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Collection date and time (derived)	14 AUG 2020 11:40
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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 05:02:10

Generated On: 09 Jun 2021 17:34:16

Collection date (dd MMM yyyy)			14 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:43	14 AUG 2020 11:43
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 05:02:10

Generated On: 09 Jun 2021 17:34:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3412243

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:34:16

**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

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 12:43

PC Open Date & Time

14 AUG 2020 12:25

PC Close Date & Time

14 AUG 2020 14:55

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.6 °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	14 AUG 2020 18:58
PC Open Date & Time	14 AUG 2020 15:50
PC Close Date & Time	15 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:34:16

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**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 AUG 2020 19:00

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:34:16

**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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 AUG 2020 19:06

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3412243

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 AUG 2020 19:58

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3412243

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 AUG 2020 18:17

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3412243

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:34:16

**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

94.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 AUG 2020 18:59

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3412243

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:34:16

**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

94.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 AUG 2020 21:46

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59



US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:34:16

**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 ☐

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

4

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

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

14 AUG 2020 12:45

PC Open Date & Time

14 AUG 2020 12:25

PC Close Date & Time

14 AUG 2020 14:55

US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:34:16

**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

14 AUG 2020 18:59

PC Open Date & Time

14 AUG 2020 15:50

PC Close Date & Time

15 AUG 2020 11:59

US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:34:16

**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

15 AUG 2020 19:01

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

16 AUG 2020 19:07

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:34:16

**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

17 AUG 2020 19:58

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:34:16

**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

18 AUG 2020 18:18

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:34:16

**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

19 AUG 2020 19:00

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

20 AUG 2020 21:46

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59



US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:16

**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 ☐

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:16

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

No ☒

Yes ☐

PC Time stamp	14 AUG 2020 12:46
PC Open Date & Time	14 AUG 2020 12:25
PC Close Date & Time	14 AUG 2020 14:55

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:16

**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 ☐

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:16

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

No ☒

Yes ☐

PC Time stamp	14 AUG 2020 18:59
PC Open Date & Time	14 AUG 2020 15:50
PC Close Date & Time	15 AUG 2020 11:59

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:16

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

52 of 2043

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:16

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 19:01
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:16

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

54 of 2043

EAB) (1725)

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:16

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



US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:16

**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 ☒

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:16

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 19:59
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:16

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 2043

EAB) (1725)

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:16

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

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:16

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 2043

EAB) (1725)

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:16

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

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:16

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

62 of 2043

EAB) (1725)

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:16

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 21:46
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59



US3412243

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 05:02:10

Generated On: 09 Jun 2021 17:34:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3412243

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 05:02:10

Generated On: 09 Jun 2021 17:34:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412243

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 05:01:51

Generated On: 09 Jun 2021 17:34:16

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3412243

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 05:01:51

Generated On: 09 Jun 2021 17:34:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412243

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 05:01:51

Generated On: 09 Jun 2021 17:34:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3412243

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 05:01:51

Generated On: 09 Jun 2021 17:34:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412243

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 05:02:11

Generated On: 09 Jun 2021 17:34:16

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3412243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 05:02:11

Generated On: 09 Jun 2021 17:34:16

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 SEP 2020
Time of assessment (00:00-23:59)	10:37 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 10:37
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 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)	88 mmHg
Diastolic Blood Pressure units	MMHG



US3412243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 05:02:11

Generated On: 09 Jun 2021 17:34:16

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)	11 SEP 2020
Time of assessment (00:00-23:59)	12:03 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 12:03
Temperature (xxx.x)	96.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3412243

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 05:02:10

Generated On: 09 Jun 2021 17:34:16

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 SEP 2020

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

US3412243

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 05:02:10

Generated On: 09 Jun 2021 17:34:16

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 11:25 (24 HR)

Treatment Date and Time (derived) 11 SEP 2020 11:25

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

US3412243

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 05:02:10

Generated On: 09 Jun 2021 17:34:16

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 SEP 2020
Collection time (00:00-23:59)	10:49 (24 HR)
Collection date and time (derived)	11 SEP 2020 10:49

US3412243

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 05:02:10

Generated On: 09 Jun 2021 17:34:16

Collection date (dd MMM yyyy)			11 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:52	11 SEP 2020 10:52
Nasopharyngeal Swab 2	No		

US3412243

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 05:02:10

Generated On: 09 Jun 2021 17:34:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412243

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:34:16

**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

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

11 SEP 2020 12:08

PC Open Date & Time

11 SEP 2020 11:45

PC Close Date & Time

11 SEP 2020 14:15

US3412243

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:34:16

**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

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 18:50

PC Open Date & Time

11 SEP 2020 15:10

PC Close Date & Time

12 SEP 2020 11:59



US3412243

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 18:20

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3412243

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:34:16

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**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 SEP 2020 18:25

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3412243

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 18:02

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3412243

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 17:26

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3412243

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °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

16 SEP 2020 16:40

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3412243

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:34:16

**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

98.9 °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

17 SEP 2020 17:32

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:34:16

**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

11 SEP 2020 12:08

PC Open Date & Time

11 SEP 2020 11:45

PC Close Date & Time

11 SEP 2020 14:15

US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

11 SEP 2020 18:50

PC Open Date & Time

11 SEP 2020 15:10

PC Close Date & Time

12 SEP 2020 11:59



US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:34:16

**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

12 SEP 2020 18:20

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:34:16

**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

13 SEP 2020 18:25

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:34:16

**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

14 SEP 2020 18:03

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

15 SEP 2020 17:27

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 16:40

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:34:16

**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

17 SEP 2020 17:32

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:16

**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 ☐

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:16

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 12:09
PC Open Date & Time	11 SEP 2020 11:45
PC Close Date & Time	11 SEP 2020 14:15



US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:16

**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 ☐

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:16

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 18:50
PC Open Date & Time	11 SEP 2020 15:10
PC Close Date & Time	12 SEP 2020 11:59

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:16

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 ☒

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:16

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 18:20
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

DAY 3

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:16

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 18:25
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:16

**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 ☒

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:16

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 18:03
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59



US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:16

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 ☒

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:16

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 17:27
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:16

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 ☒

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:16

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 16:41
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:16

**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 ☒

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:16

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 17:32
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3412243

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 05:02:10

Generated On: 09 Jun 2021 17:34:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3412243

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 05:02:10

Generated On: 09 Jun 2021 17:34:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3412243

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 05:02:10

Generated On: 09 Jun 2021 17:34:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3412243

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 05:02:10

Generated On: 09 Jun 2021 17:34:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412243

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 05:02:10

Generated On: 09 Jun 2021 17:34:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3412243

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 05:02:10

Generated On: 09 Jun 2021 17:34:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412243

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 05:02:11

Generated On: 09 Jun 2021 17:34:16

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3412243

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 05:02:11

Generated On: 09 Jun 2021 17:34:16

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) \_\_\_\_\_

US3412243

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 05:02:11

Generated On: 09 Jun 2021 17:34:16

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.*

US3412243

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 05:02:11

Generated On: 09 Jun 2021 17:34:16

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	9 OCT 2020
Collection time (00:00-23:59)	09:45 (24 HR)
Collection date and time (derived)	9 OCT 2020 09:45



US3412243

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 05:02:11

Generated On: 09 Jun 2021 17:34:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412243

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 OCT 2020 12:52:14
Patient Cloud Open Date & Time	14 OCT 2020 00:01
Patient Cloud Close Date & Time	18 OCT 2020 23:59

US3412243

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**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

22 OCT 2020 18:06:25

Patient Cloud Open Date & Time

21 OCT 2020 00:01

Patient Cloud Close Date & Time

25 OCT 2020 23:59

US3412243

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 OCT 2020 10:57:08

Patient Cloud Open Date & Time

28 OCT 2020 00:01

Patient Cloud Close Date & Time

01 NOV 2020 23:59

US3412243

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 NOV 2020 07:48:16

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3412243

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

DAY 99

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 NOV 2020 06:54:13

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

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	19 NOV 2020 12:14:53
Patient Cloud Open Date & Time	15 NOV 2020 00:01
Patient Cloud Close Date & Time	19 NOV 2020 23:59

US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**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

22 NOV 2020 14:25:04

Patient Cloud Open Date & Time

22 NOV 2020 00:01

Patient Cloud Close Date & Time

26 NOV 2020 23:59



US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 NOV 2020 16:17:38
Patient Cloud Open Date & Time	29 NOV 2020 00:01
Patient Cloud Close Date & Time	03 DEC 2020 23:59

US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 DEC 2020 16:55:00

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

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	13 DEC 2020 13:14:23
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59

US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 DEC 2020 15:15:48

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**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

27 DEC 2020 13:21:01

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**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

03 JAN 2021 15:36:44

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 JAN 2021 12:03:05

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**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

20 JAN 2021 12:43:37

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59



US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 JAN 2021 14:27:12

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**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

01 FEB 2021 06:54:56

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 FEB 2021 13:51:20

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59

US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 FEB 2021 16:47:01

Patient Cloud Open Date & Time

14 FEB 2021 00:01

Patient Cloud Close Date & Time

18 FEB 2021 23:59

US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 FEB 2021 10:49:11

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 FEB 2021 11:52:21

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 MAR 2021 10:47:35

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**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

15 MAR 2021 15:30:44

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59



US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**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

23 MAR 2021 13:31:54

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**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

28 MAR 2021 01:18:15

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

<b>TIMEPOINT</b>	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 APR 2021 09:12:38
Patient Cloud Open Date & Time	04 APR 2021 00:01
Patient Cloud Close Date & Time	08 APR 2021 23:59

US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**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

12 APR 2021 11:37:54

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 APR 2021 10:28:54

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 APR 2021 12:30:38

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**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 ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 MAY 2021 11:12:42

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

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



**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

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

---

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

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US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**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 ☐

**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

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

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[Patient Cloud Close Date & Time](#)

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20 MAY 2021 23:59

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US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

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="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"/>

**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

DAY 292

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

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

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

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

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

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

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

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

**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

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

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[Patient Cloud Close Date & Time](#)

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03 JUN 2021 23:59

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US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

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

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[Patient Cloud Close Date & Time](#)

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10 JUN 2021 23:59

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US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

DAY 306

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

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

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

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

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

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

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

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

**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

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

US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**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 ☐

**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

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

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

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="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"/>

**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

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

27 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

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US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

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

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



**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

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

**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

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

US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

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"/>

**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	18 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 JUL 2021 23:59

US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

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

**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

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

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**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 ☐



**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

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

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[Patient Cloud Close Date & Time](#)

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05 AUG 2021 23:59

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US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

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

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

**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	19 AUG 2021 23:59
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US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

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

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

**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

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

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[Patient Cloud Open Date & Time](#)

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29 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 SEP 2021 23:59

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US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

DAY 390

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

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

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

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

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

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

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 ☐

**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	09 SEP 2021 23:59
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US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

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 ☐

**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

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

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[Patient Cloud Open Date & Time](#)

12 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

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US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

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="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"/>

**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

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

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[Patient Cloud Close Date & Time](#)

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23 SEP 2021 23:59

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US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

DAY 411

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

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

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

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

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

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

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 ☐



**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

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

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[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

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US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

DAY 418

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

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

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

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

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

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

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 ☐

**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

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

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[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

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US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

DAY 425

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

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

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

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

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

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

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

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

**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	10 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 OCT 2021 23:59

US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

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

US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

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

US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

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

**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

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

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

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

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

**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

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

**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

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

14 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**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 ☐



**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

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

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[Patient Cloud Open Date & Time](#)

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21 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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25 NOV 2021 23:59

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US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

DAY 474

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

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

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

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

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

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

**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

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

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[Patient Cloud Open Date & Time](#)

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28 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 DEC 2021 23:59

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US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

DAY 481

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

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

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

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

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

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

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 ☐

**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

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

US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

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"/>

**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

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

US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

DAY 495

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

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

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

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

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

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

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

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



**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

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

US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

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

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

**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

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

[Patient Cloud Close Date & Time](#)

30 DEC 2021 23:59

US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

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

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[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

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US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

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

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[Patient Cloud Open Date & Time](#)

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09 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 JAN 2022 23:59

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US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

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

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

DAY 530

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

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

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

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

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

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

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 ☐

**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

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

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[Patient Cloud Close Date & Time](#)

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27 JAN 2022 23:59

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US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**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 ☐

**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

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

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[Patient Cloud Close Date & Time](#)

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10 FEB 2022 23:59

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US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**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 ☐

**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

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

US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**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 ☐

**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

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

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

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

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[Patient Cloud Close Date & Time](#)

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10 MAR 2022 23:59

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US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**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 ☐



**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

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

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[Patient Cloud Close Date & Time](#)

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17 MAR 2022 23:59

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US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 MAR 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	24 MAR 2022 23:59
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US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	27 MAR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	31 MAR 2022 23:59

US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

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"/>

**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

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

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[Patient Cloud Open Date & Time](#)

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03 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 APR 2022 23:59

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US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

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



**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	10 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 APR 2022 23:59

US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

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"/>

**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	17 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 APR 2022 23:59

US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

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="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"/>

**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

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

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[Patient Cloud Open Date & Time](#)

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24 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 APR 2022 23:59

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US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

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

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[Patient Cloud Close Date & Time](#)

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05 MAY 2022 23:59

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US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**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 ☐



**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

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

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[Patient Cloud Open Date & Time](#)

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15 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 MAY 2022 23:59

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US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

DAY 649

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

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

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

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

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

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

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 ☐

**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

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

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[Patient Cloud Open Date & Time](#)

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22 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 MAY 2022 23:59

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US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**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 ☐



**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

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

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[Patient Cloud Open Date & Time](#)

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05 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 JUN 2022 23:59

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US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

DAY 670

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

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

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[Patient Cloud Close Date & Time](#)

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16 JUN 2022 23:59

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US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

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 ☐

**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

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

19 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

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US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

TIMEPOINT

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

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

US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

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"/>



**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

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

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	10 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 JUL 2022 23:59

US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

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

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

**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

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

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[Patient Cloud Close Date & Time](#)

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21 JUL 2022 23:59

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US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

DAY 726

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

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

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[Patient Cloud Open Date & Time](#)

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07 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 AUG 2022 23:59

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US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

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

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[Patient Cloud Open Date & Time](#)

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14 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 AUG 2022 23:59

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US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

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

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[Patient Cloud Open Date & Time](#)

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21 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 AUG 2022 23:59

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US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

DAY 747

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

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

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

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

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

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

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 ☐



**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

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

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

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

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[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

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US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

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

11 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

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US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

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="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"/>

**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

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

18 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

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US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**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 ☐



**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**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 ☐

**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**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 ☐

**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

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

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[Patient Cloud Open Date & Time](#)

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09 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 OCT 2022 23:59

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US3412243

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

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"/>

**US3412243**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	16 OCT 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	20 OCT 2022 23:59
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US3412243

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:34:16

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 11:54:51



US3412243

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 19:38:05

Generated On: 09 Jun 2021 17:34:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3412243

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 19:38:05

Generated On: 09 Jun 2021 17:34:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412243

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:51:06

Generated On: 09 Jun 2021 17:34:16

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 9 DEC 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3412243

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:51:06

Generated On: 09 Jun 2021 17:34:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412243

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:51:06

Generated On: 09 Jun 2021 17:34:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3412243

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:51:06

Generated On: 09 Jun 2021 17:34:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412243

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:51:06

Generated On: 09 Jun 2021 17:34:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3412243

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:51:06

Generated On: 09 Jun 2021 17:34:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3412243

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:51:06

Generated On: 09 Jun 2021 17:34:16

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3412243

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 14:51:06

Generated On: 09 Jun 2021 17:34:16

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	04 MAR 2021
Time of assessment (00:00-23:59)	10:56 (24 HR)
Vital Signs Date and Time (derived)	04 MAR 2021 10:56
Temperature (xxx.x)	36.4 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	110 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3412243

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 14:51:06

Generated On: 09 Jun 2021 17:34:16

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

04 MAR 2021

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

US3412243

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 14:51:06

Generated On: 09 Jun 2021 17:34:16

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	04 MAR 2021
Collection time (00:00-23:59)	10:37 (24 HR)
Collection date and time (derived)	04 MAR 2021 10:37

US3412243

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:51:06

Generated On: 09 Jun 2021 17:34:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412243

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:51:06

Generated On: 09 Jun 2021 17:34:16

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 9 APR 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3412243

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:51:06

Generated On: 09 Jun 2021 17:34:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3412243**

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

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:34:16**

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*



**US3412243**

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

**Form: Continuing**

**Generated On: 09 Jun 2021 17:34:16**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**US3412243**

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

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 17:34:16**

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"/>

**US3412243**

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

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

**Generated On: 09 Jun 2021 17:34:16**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3412243

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

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:51:06

Generated On: 09 Jun 2021 17:34:16

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

Visit date (dd MMM yyyy)	04 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	UNBLND_DECIDE
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US3412243

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

Form: Unblinding

Data signed: (b) (4) 16 Apr 2021 14:51:05

Generated On: 09 Jun 2021 17:34:16

Date of updated informed consent ( <i>dd MMM yyyy</i> )	04 MAR 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> )	04 MAR 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

**US3412243**

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

**Form: Vital Signs - Dosing**

**Data signed:** (b) (4) 16 Apr 2021 14:51:06

**Generated On: 09 Jun 2021 17:34:16**

Height	144 cm
Weight	83.6 kg
BMI (xxx.x)	40.31636

US3412243

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Apr 2021 14:51:06

Generated On: 09 Jun 2021 17:34:16

Height	144 cm
Weight	83.6 kg
BMI (xxx.x)	40.31636
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)	04 MAR 2021
Time of assessment (00:00-23:59)	10:56 (24 HR)
Vital Signs Date and Time (derived)	04 MAR 2021 10:56
Temperature (xxx.x)	36.4 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify _____	
Pulse (xxx)	110 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3412243

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Apr 2021 14:51:06

Generated On: 09 Jun 2021 17:34:16

Height	144 cm
Weight	83.6 kg
BMI (xxx.x)	40.31636
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input type="checkbox"/> No <input type="checkbox"/>
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 <input type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
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	



US3412243

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

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 14:51:05

Generated On: 09 Jun 2021 17:34:16

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

04 MAR 2021

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

US3412243

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

Form: Exposure

Data signed: (b) (4) 16 Apr 2021 14:51:05

Generated On: 09 Jun 2021 17:34:16

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) 04 MAR 2021

What was the treatment time? (00:00-23:59) 11:50 (24 HR)

Treatment Date and Time (derived) 04 MAR 2021 11:50

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

US3412243

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 14:51:05

Generated On: 09 Jun 2021 17:34:16

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

04 MAR 2021

Collection time (00:00-23:59)

10:37 (24 HR)

Collection date and time (derived)

04 MAR 2021 10:37

US3412243

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 16 Apr 2021 14:51:05

Generated On: 09 Jun 2021 17:34:16

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	04 MAR 2021
Collection time (00:00 - 23:59)	10:38
Collection Date and Time (derived)	04 MAR 2021 10:38

US3412243

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

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:51:05

Generated On: 09 Jun 2021 17:34:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412243

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:51:06

Generated On: 09 Jun 2021 17:34:16

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

US3412243

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:51:06

Generated On: 09 Jun 2021 17:34:16

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

US3412243

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:51:05

Generated On: 09 Jun 2021 17:34:16

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29



US3412243

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Apr 2021 14:51:05

Generated On: 09 Jun 2021 17:34:16

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)	5 APR 2021
Time of assessment (00:00-23:59)	12:06 (24 HR)
Vital Signs Date and Time (derived)	5 APR 2021 12:06
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	88 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)	92 mmHg
Diastolic Blood Pressure units	MMHG

US3412243

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Apr 2021 14:51:05

Generated On: 09 Jun 2021 17:34:16

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)	5 APR 2021
Time of assessment (00:00-23:59)	13:34 (24 HR)
Vital Signs Date and Time (derived)	5 APR 2021 13:34
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	81 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)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3412243

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 14:51:05

Generated On: 09 Jun 2021 17:34:16

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.*

US3412243

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 16 Apr 2021 14:51:05

Generated On: 09 Jun 2021 17:34:16

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) 5 APR 2021

What was the treatment time? (00:00-23:59) 12:56 (24 HR)

Treatment Date and Time (derived) 5 APR 2021 12:56

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

US3412243

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:51:05

Generated On: 09 Jun 2021 17:34:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3412243**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:34:16**

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*

**US3412243**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:34:16**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3412243

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 15 Mar 2021 15:37:33

Generated On: 09 Jun 2021 17:34:16

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---



US3412243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:16

AEID	USA-US061-2021-MRNA-1273-P30 1000012
Adverse event	WORSENING OF OSTEOARTHRITIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	15 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	18 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	13 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	18 JAN 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
PRODUCTION RELEASE (v12.003 EAB) (1725)	344 of 2043

US3412243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:16

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
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	

US3412243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:16

---

SUBJECT PRESENTED  
04-MAR-2021 FOR DAY 209  
VISIT. SUBJECT EXPRESSED  
THAT SHE HAD WORSENING OF  
HER OSTOARTHRITIS AND  
THAT IT CAUSED HER TO HAVE  
A LEFT TOTAL KNEE  
REPLACEMENT SURGERY IN  
WHICH SHE WAS  
HOSPITALIZED FOR 5 DAYS  
FOR RECOVERY. SUBJECT  
STATES THIS WAS SCHEDULED  
PRIOR TO THIS STUDY. KNEE  
PAIN IS BETTER SINCE  
SURGERY, BUT NOT  
RESOLVED.

---

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

---

US3412243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 12 Apr 2021 14:41:13

Generated On: 09 Jun 2021 17:34:16

---

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

Yes ☒

No ☐

---

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

---

US3412243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Apr 2021 14:23:19

Generated On: 09 Jun 2021 17:34:16

Name of Medication ALBUTEROL

Prophylaxis Yes ☐  
No ☒

Indication ASTHMA

Dose per administration 90

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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US3412243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Apr 2021 14:23:19

Generated On: 09 Jun 2021 17:34:16

	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 1975	
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"/>

US3412243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Apr 2021 14:23:19

Generated On: 09 Jun 2021 17:34:16

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3412243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Apr 2021 14:23:19

Generated On: 09 Jun 2021 17:34:16

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2017
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



US3412243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 12 Apr 2021 14:23:19

Generated On: 09 Jun 2021 17:34:16

Name of Medication FLONASE

Prophylaxis Yes ☐  
No ☒

Indication PERENNIAL ALLERGIC  
RHINITIS

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3412243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 12 Apr 2021 14:23:19

Generated On: 09 Jun 2021 17:34:16

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input checked="" 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 2016
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)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3412243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 12 Apr 2021 14:23:19

Generated On: 09 Jun 2021 17:34:16

Name of Medication METFORMIN

Prophylaxis Yes ☐  
No ☒

Indication DIABETES TYPE 2

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3412243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 12 Apr 2021 14:23:19

Generated On: 09 Jun 2021 17:34:16

	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 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 12 Apr 2021 14:23:19

Generated On: 09 Jun 2021 17:34:16

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐  
No ☒

Indication GASTROESOPHAGEAL REFLUX  
DISEASE

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 12 Apr 2021 14:23:19

Generated On: 09 Jun 2021 17:34:16

	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 2017
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 12 Apr 2021 14:23:19

Generated On: 09 Jun 2021 17:34:16

Name of Medication SINGULAIR

Prophylaxis Yes ☐  
No ☒

Indication ASTHMA

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 12 Apr 2021 14:23:19

Generated On: 09 Jun 2021 17:34:16

	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 2016	
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"/>



US3412243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 12 Apr 2021 14:23:19

Generated On: 09 Jun 2021 17:34:16

Name of Medication ZYRTEC

Prophylaxis Yes ☐  
No ☒

Indication PERENNIAL ALLERGIC  
RHINITIS

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3412243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 12 Apr 2021 14:23:19

Generated On: 09 Jun 2021 17:34:16

	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 2016
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"/>

US3412243

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 12 Apr 2021 14:41:13

Generated On: 09 Jun 2021 17:34:16

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3412243

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 12 Apr 2021 14:41:13

Generated On: 09 Jun 2021 17:34:16

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
13 JAN 2021	LEFT TOTAL KNEE REPLACEMENT	Adverse Event	

US3412243

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:34:16

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3412243

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:34:16

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 ☐

US3412243

Folder: SAE USA-US061-2021-MRNA-1273-P301000012

Form: Safety Report Form

Data signed: (b) (4) 26 Apr 2021 14:42:20

Generated On: 09 Jun 2021 17:34:16

SAEID	USA-US061-2021-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3412243

Folder: SAE USA-US061-2021-MRNA-1273-P301000012

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Apr 2021 14:42:20

Generated On: 09 Jun 2021 17:34:16

SAEID	USA-US061-2021-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	05/MAR/2021 11:54
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True



US3412243

Folder: SAE USA-US061-2021-MRNA-1273-P301000012

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Apr 2021 14:42:20

Generated On: 09 Jun 2021 17:34:16

SAEID	USA-US061-2021-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	26/MAR/2021 08:37
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3412243

Folder: SAE USA-US061-2021-MRNA-1273-P301000012

Form: Safety Report Form (3)

Data signed: (b) (4) 26 Apr 2021 14:42:20

Generated On: 09 Jun 2021 17:34:16

SAEID	USA-US061-2021-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	06/APR/2021 13:42
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3412243

Folder: SAE USA-US061-2021-MRNA-1273-P301000012

Form: Safety Report Form (4)

Data signed: (b) (4) 26 Apr 2021 14:42:20

Generated On: 09 Jun 2021 17:34:16

SAEID	USA-US061-2021-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	22/APR/2021 14:07
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3412243 (Prod: New Horizons Clinical Research)

**US3412243**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 17:34:16**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered 'US3412243'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 15:19:30

**US3412243**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:34:16**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'Yes (Y)'	Steven Anderson (b) (4)	14 Aug 2020 16:05:56

US3412243

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:34:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '14 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 15:19:31

**US3412243**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:34:16**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'Clinic (Clinic)'	Steven Anderson (b) (4)	14 Aug 2020 16:05:56



**US3412243**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:34:16**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User entered 'SCRN'	System	14 Aug 2020 16:05:56

**US3412243**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:34:16**

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered (b) (6) 1954'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 15:19:32

**US3412243**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:34:16**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '65'	Steven Anderson (b) (4)	14 Aug 2020 16:06:08

**US3412243**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:34:16**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User entered 'YEARS'	System	14 Aug 2020 16:06:08

**US3412243**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:34:16**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User entered '66'	System	14 Aug 2020 16:06:24

**US3412243**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:34:16**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'Female (F)'	Steven Anderson (b) (4)	14 Aug 2020 16:06:08

US3412243

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:34:16

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Steven Anderson (b) (4)	14 Aug 2020 16:06:08

**US3412243**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:34:16**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '0'	Steven Anderson (b) (4)	14 Aug 2020 16:06:08



**US3412243**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:34:16**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'I'	Steven Anderson (b) (4)	14 Aug 2020 16:06:08

**US3412243**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:34:16**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '0'	Steven Anderson (b) (4)	14 Aug 2020 16:06:08

**US3412243**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:34:16**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '0'	Steven Anderson (b) (4)	14 Aug 2020 16:06:08

**US3412243**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:34:16**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '0'	Steven Anderson (b) (4)	14 Aug 2020 16:06:08

**US3412243**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:34:16**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '0'	Steven Anderson (b) (4)	14 Aug 2020 16:06:08

**US3412243**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:34:16**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered empty.	Steven Anderson (b) (4)	14 Aug 2020 16:06:08

**US3412243**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:34:16**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '0'	Steven Anderson (b) (4)	14 Aug 2020 16:06:08

**US3412243**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:34:16**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '0'	Steven Anderson (b) (4)	14 Aug 2020 16:06:08



US3412243

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:34:16

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '14 Aug 2020'	Steven Anderson (b) (4)	14 Aug 2020 16:06:24

**US3412243**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:34:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User entered 'Aug 2020'	System	14 Aug 2020 16:06:24

**US3412243**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:34:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User entered '2020'	System	14 Aug 2020 16:06:24

**US3412243**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:34:16**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'Amendment 2 (2)'	Steven Anderson (b) (4)	14 Aug 2020 16:06:24

US3412243

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:34:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'Yes (Y)'	Steven Anderson (b) (4)	14 Aug 2020 16:06:24

**US3412243**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:34:16**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered empty.	Steven Anderson (b) (4)	14 Aug 2020 16:06:24

**US3412243**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:34:16**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered empty.	Steven Anderson (b) (4)	14 Aug 2020 16:06:24

**US3412243**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:34:16**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'No (N)'	Steven Anderson (b) (4)	14 Aug 2020 16:06:24



**US3412243**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:34:16**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 15:19:31

US3412243

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:34:16

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User entered 'I'	System	14 Aug 2020 16:06:30

US3412243

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:34:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'Yes (Y)'	Steven Anderson (b) (4)	14 Aug 2020 16:06:30

US3412243

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:34:16

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:44:15

US3412243

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:34:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Upper respiratory tract disorders (excl infections), HLT: Nasal congestion and inflammations, PT: Rhinitis perennial, LLT: Perennial allergic rhinitis - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 17:45:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 17:45:19
Data point term sent to Coder	System	20 Aug 2020 17:44:46
User entered 'PERENNIAL ALLERGIC RHINITIS'	(b) (4), (b) (6)	20 Aug 2020 17:44:45

**US3412243**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:34:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'un UNK 1960' reason for change: Data Entry Error	Jacob sekinger (b) (4)	24 Sep 2020 13:37:33
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 17:45:47
User entered 'UN UNK 2016'		20 Aug 2020 17:44:45

**US3412243**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:34:16**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '0' reason for change: Data Entry Error	(b) (4)	
	Jacob sekinger (b) (4)	24 Sep 2020 13:37:33
User entered '1' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	20 Aug 2020 17:45:47
User entered '0'		20 Aug 2020 17:44:45

**US3412243**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:34:16**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:44:45



**US3412243**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:34:16**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:44:45

**US3412243**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:34:16**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:44:45

**US3412243**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:34:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User entered 'Jan 1960'	System	24 Sep 2020 13:37:33
User entered empty.	System	20 Aug 2020 17:45:47
User entered 'Jan 2016'	System	20 Aug 2020 17:44:45

**US3412243**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:34:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User entered '1960'	System	24 Sep 2020 13:37:33
User entered empty.	System	20 Aug 2020 17:45:47
User entered '2016'	System	20 Aug 2020 17:44:45

**US3412243**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:34:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User entered empty.	System	20 Aug 2020 17:44:45

**US3412243**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:34:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User entered empty.	System	20 Aug 2020 17:44:45

US3412243

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:34:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 10:36:24
User closed query 'Per DM CLR: Please update the condition to include the laterality of GLAUCOMA (e.g. Left, Right or Bilateral Glaucoma). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).		20 Oct 2020 10:36:22
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'PATIENT DID NOT STATE' (Site from DM).	Mylene Asmar-Rios (b) (4)	15 Oct 2020 18:52:06
Query 'Per DM CLR: Please update the condition to include the laterality of GLAUCOMA (e.g. Left, Right or Bilateral Glaucoma). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'PATIENT DID NOT STATED' (Site from DM).	Mylene Asmar-Rios (b) (4)	15 Oct 2020 18:51:52
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 16:33:54

US3412243

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:34:16

[Condition](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please update the condition to include the laterality of GLAUCOMA (e.g. Left, Right or Bilateral Glaucoma). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 16:33:10
User coded data point as SOC: Eye disorders, HLGT: Glaucoma and ocular hypertension, HLT: Glaucomas (excl congenital), PT: Glaucoma, LLT: Glaucoma - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 17:47:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	20 Aug 2020 17:47:27
Data point term sent to Coder	System	20 Aug 2020 17:46:50
User entered 'GLAUCOMA'	(b) (4), (b) (6)	20 Aug 2020 17:46:23



US3412243

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:34:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'UN UNK 2016'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:46:23

**US3412243**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:34:16**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:46:23

**US3412243**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:34:16**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:46:23

**US3412243**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:34:16**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:46:23

**US3412243**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:34:16**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:46:23

**US3412243**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:34:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User entered 'Jan 2016'	System	20 Aug 2020 17:46:23

**US3412243**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:34:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User entered '2016'	System	20 Aug 2020 17:46:23

**US3412243**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:34:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User entered empty.	System	20 Aug 2020 17:46:23



**US3412243**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:34:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User entered empty.	System	20 Aug 2020 17:46:23

US3412243

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:34:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 17:47:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 17:47:28
Data point term sent to Coder	System	20 Aug 2020 17:46:50
User entered 'ASTHMA'	(b) (4), (b) (6)	20 Aug 2020 17:46:41

**US3412243**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:34:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'UN UNK 1962'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:46:41

**US3412243**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:34:16**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:46:41

**US3412243**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:34:16**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:46:41

**US3412243**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:34:16**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:46:41

**US3412243**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:34:16**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:46:41

**US3412243**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:34:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User entered 'Jan 1962'	System	20 Aug 2020 17:46:41



**US3412243**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:34:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User entered '1962'	System	20 Aug 2020 17:46:41

**US3412243**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:34:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User entered empty.	System	20 Aug 2020 17:46:41

**US3412243**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:34:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User entered empty.	System	20 Aug 2020 17:46:41

US3412243

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:34:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Sleep apnea - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 17:49:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 17:49:31
Data point term sent to Coder	System	20 Aug 2020 17:47:51
User entered 'SLEEP APNEA'	(b) (4), (b) (6)	20 Aug 2020 17:46:58

**US3412243**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:34:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'UN UNK 2012'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:46:58

**US3412243**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:34:16**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:46:58

**US3412243**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:34:16**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:46:58

**US3412243**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:34:16**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:46:58



**US3412243**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:34:16**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:46:58

**US3412243**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:34:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User entered 'Jan 2012'	System	20 Aug 2020 17:46:58

**US3412243**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:34:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User entered '2012'	System	20 Aug 2020 17:46:58

**US3412243**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:34:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User entered empty.	System	20 Aug 2020 17:46:58

**US3412243**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:34:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User entered empty.	System	20 Aug 2020 17:46:58

US3412243

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:34:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
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)	20 Aug 2020 17:53:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 17:53:26
Data point term sent to Coder	System	20 Aug 2020 17:53:04
User entered 'HYPERLIPIDEMIA'	(b) (4), (b) (6)	20 Aug 2020 17:52:34

**US3412243**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:34:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'UN UNK 2017'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:52:34

**US3412243**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:34:16**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:52:34



**US3412243**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:34:16**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:52:34

**US3412243**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:34:16**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:52:34

**US3412243**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:34:16**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:52:34

**US3412243**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:34:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User entered 'Jan 2017'	System	20 Aug 2020 17:52:34

**US3412243**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:34:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User entered '2017'	System	20 Aug 2020 17:52:34

**US3412243**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:34:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User entered empty.	System	20 Aug 2020 17:52:34

**US3412243**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:34:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User entered empty.	System	20 Aug 2020 17:52:34

US3412243

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:34:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Oct 2020 10:36:44
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'subject did not state any meds' (Site from DM).	Mylene Asmar-Rios (b) (4)	15 Oct 2020 20:19:04
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 16:34:51
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 17:53:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 17:53:27
Data point term sent to Coder	System	20 Aug 2020 17:53:04
User entered 'HYPERTENSION'	(b) (4), (b) (6)	20 Aug 2020 17:53:00



**US3412243**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:34:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'UN UNK 2013'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:53:00

**US3412243**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:34:16**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:53:00

**US3412243**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:34:16**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:53:00

**US3412243**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:34:16**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:53:00

**US3412243**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:34:16**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:53:00

**US3412243**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:34:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User entered 'Jan 2013'	System	20 Aug 2020 17:53:00

**US3412243**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:34:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User entered '2013'	System	20 Aug 2020 17:53:00

**US3412243**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:34:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User entered empty.	System	20 Aug 2020 17:53:00



**US3412243**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:34:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User entered empty.	System	20 Aug 2020 17:53:00

US3412243

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:34:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 17:55:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 17:55:23
Data point term sent to Coder	System	20 Aug 2020 17:54:05
User entered 'Gastroesophageal reflux disease'	(b) (4), (b) (6)	20 Aug 2020 17:53:15

**US3412243**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:34:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'UN UNK 2015'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:53:15

**US3412243**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:34:16**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:53:15

**US3412243**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:34:16**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:53:15

**US3412243**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:34:16**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:53:15

**US3412243**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:34:16**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:53:15

**US3412243**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:34:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User entered 'Jan 2015'	System	20 Aug 2020 17:53:15



**US3412243**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:34:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User entered '2015'	System	20 Aug 2020 17:53:15

**US3412243**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:34:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User entered empty.	System	20 Aug 2020 17:53:15

**US3412243**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:34:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User entered empty.	System	20 Aug 2020 17:53:15

US3412243

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:34:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 05:10:21
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 05:10:21
Data point term sent to Coder	System	20 Aug 2020 17:54:05
User entered 'OSTEOARTHRITIS: ELBOWS, KNEES'	(b) (4), (b) (6)	20 Aug 2020 17:53:34

**US3412243**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:34:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'UN UNK 2005'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:53:34

**US3412243**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:34:16**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:53:34

**US3412243**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:34:16**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:53:34

**US3412243**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:34:16**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:53:34



**US3412243**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:34:16**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:53:34

**US3412243**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:34:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User entered 'Jan 2005'	System	20 Aug 2020 17:53:34

**US3412243**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:34:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User entered '2005'	System	20 Aug 2020 17:53:34

**US3412243**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:34:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User entered empty.	System	20 Aug 2020 17:53:34

**US3412243**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:34:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User entered empty.	System	20 Aug 2020 17:53:34

US3412243

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:34:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 17:55:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 17:55:22
Data point term sent to Coder	System	20 Aug 2020 17:54:07
User entered 'DIABETES TYPE 2'	(b) (4), (b) (6)	20 Aug 2020 17:53:50

**US3412243**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:34:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'UN UNK 2014'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:53:50

**US3412243**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:34:16**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:53:50



**US3412243**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:34:16**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:53:50

**US3412243**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:34:16**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:53:50

**US3412243**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:34:16**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:53:50

**US3412243**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:34:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User entered 'Jan 2014'	System	20 Aug 2020 17:53:50

**US3412243**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:34:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User entered '2014'	System	20 Aug 2020 17:53:50

**US3412243**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:34:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User entered empty.	System	20 Aug 2020 17:53:50

**US3412243**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:34:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User entered empty.	System	20 Aug 2020 17:53:50

US3412243

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:34:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 15:36:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 15:36:37
Data point term sent to Coder	System	21 Oct 2020 15:36:06
User entered 'post menopausal'	Jacob sekinger (b) (4)	21 Oct 2020 15:35:41



US3412243

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:34:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'un UNK 2000'	Jacob sekinger (b) (4)	21 Oct 2020 15:35:41

**US3412243**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:34:16**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '0'	Jacob sekinger (b) (4)	21 Oct 2020 15:35:41

**US3412243**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:34:16**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	21 Oct 2020 15:35:41

**US3412243**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:34:16**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered empty.	Jacob sekinger (b) (4)	21 Oct 2020 15:35:41

US3412243

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:34:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '0'	Jacob sekinger (b) (4)	21 Oct 2020 15:35:41

**US3412243**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:34:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User entered 'Jan 2000'	System	21 Oct 2020 15:35:41

**US3412243**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:34:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User entered '2000'	System	21 Oct 2020 15:35:41

**US3412243**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:34:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User entered empty.	System	21 Oct 2020 15:35:41



**US3412243**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:34:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User entered empty.	System	21 Oct 2020 15:35:41

**US3412243**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:34:16**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:40:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:03:16

US3412243

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:40:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '14 Aug 2020'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:03:16

**US3412243**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:34:16**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:40:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '11:10'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:03:16

**US3412243**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:34:16**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:40:02
User entered '14 Aug 2020 11:10'	System	20 Aug 2020 18:03:16

US3412243

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:16

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:40:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User closed query 'Height reported is out of range <= 121.92cm (48in) OR >= 228.6cm (90in). Please reconcile.' (Site from System).	(b) (4)	24 Sep 2020 13:39:25
Query 'Height reported is out of range <= 121.92cm (48in) OR >= 228.6cm (90in). Please reconcile.' answered by data change (Site from System).	System	24 Sep 2020 13:39:25
User entered '145.5' cm reason for change: Data Entry Error	Jacob sekinger (b) (4)	24 Sep 2020 13:39:25
Amendment Manager: User opened query 'Height reported is out of range <= 121.92cm (48in) OR >= 228.6cm (90in). Please reconcile.' (Site from System).	(b) (4)	
User entered '105.5' cm	System	16 Sep 2020 23:57:08
DataPoint set to visible.	(b) (4), (b) (6)	20 Aug 2020 18:03:16
		14 Aug 2020 16:06:30

US3412243

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:16

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:40:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '84.5' kg	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:03:16
DataPoint set to visible.	System	14 Aug 2020 16:06:30

**US3412243**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:34:16**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:40:02
User entered '39.91450'	System	24 Sep 2020 13:39:25
Amendment Manager: User entered '75.91923'	System	16 Sep 2020 23:57:08
User entered '75.9'	System	20 Aug 2020 18:03:16
DataPoint set to visible.	System	14 Aug 2020 16:06:30



**US3412243**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:34:16**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:40:02
User entered 'kg/m2'	System	20 Aug 2020 18:03:16
DataPoint set to visible.	System	14 Aug 2020 16:06:30

**US3412243**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:34:16**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:40:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:03:16

US3412243

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:40:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	21 Aug 2020 08:57:59
Query 'Data is required. Please provide.' answered with 'NA' (Site from System).		20 Aug 2020 18:03:21
User opened query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 18:03:16
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:03:16

**US3412243**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:34:16**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:40:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:03:16

US3412243

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:40:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:03:16

**US3412243**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:34:16**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:40:02
User entered 'bpm'	System	20 Aug 2020 18:03:16

US3412243

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:40:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:03:16

**US3412243**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:34:16**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:40:02
User entered 'breaths/min'	System	20 Aug 2020 18:03:16



**US3412243**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:34:16**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:40:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:03:16

**US3412243**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:34:16**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:40:02
User entered 'mmHg'	System	20 Aug 2020 18:03:16

**US3412243**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:34:16**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:40:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:03:16

**US3412243**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:34:16**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:40:02
User entered 'mmHg'	System	20 Aug 2020 18:03:16

**US3412243**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:34:16**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:40:02

**US3412243**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:34:16**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:40:02

**US3412243**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:34:16**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:03:32

US3412243

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 22:44:30
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	11 Sep 2020 15:00:28
User entered '14 Aug 2020'	(b) (4), (b) (6)	20 Aug 2020 18:03:32



US3412243

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:34:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '14 Aug 2020'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:06:08

US3412243

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:34:16

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:06:08

US3412243

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:34:16

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User closed query 'Per CDM re-query: Response states 'UPDATED', however there is still nor record of this condition on the MH eCRF. Please review and update.' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Nov 2020 12:38:40
Query 'Per CDM re-query: Response states 'UPDATED', however there is still nor record of this condition on the MH eCRF. Please review and update.' answered with 'this has been resolved. ' (Site from DM).	Jacob sekinger (b) (4) (b) (4)	21 Oct 2020 15:36:00
User opened query 'Per CDM re-query: Response states 'UPDATED', however there is still nor record of this condition on the MH eCRF. Please review and update.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 10:40:25
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 10:40:25
Query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' answered with 'UPDATED' (Site from DM).	Mylene Asmar-Rios (b) (4)	15 Oct 2020 18:50:17
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 05:42:38
User entered 'Post-menopausal (POST-MENOPAUSAL)'	(b) (4), (b) (6)	20 Aug 2020 18:06:08

**US3412243**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 17:34:16**

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:06:08

US3412243

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:34:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:06:08

**US3412243**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 17:34:16**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:06:08

US3412243

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:34:16

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'UN UNK 2000'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:06:08

**US3412243**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 17:34:16**

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:06:08



US3412243

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:16

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Aug 2020 18:08:40
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 18:08:40
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Aug 2020 18:08:04
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:08:04

US3412243

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:16

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Aug 2020 18:08:40
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 18:08:40
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Aug 2020 18:08:04
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:08:04

US3412243

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:16

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Aug 2020 18:08:40
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 18:08:40
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Aug 2020 18:08:04
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:08:04

US3412243

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:16

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Aug 2020 18:08:40
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 18:08:40
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Aug 2020 18:08:04
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:08:04

US3412243

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:16

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	20 Aug 2020 18:08:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Aug 2020 18:08:40
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 18:08:40
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Aug 2020 18:08:04
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:08:04

US3412243

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:16

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Aug 2020 18:08:40
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 18:08:40
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Aug 2020 18:08:04
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:08:04

US3412243

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:16

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Aug 2020 18:08:40
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 18:08:40
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Aug 2020 18:08:04
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:08:04

US3412243

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:16

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Aug 2020 18:08:40
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 18:08:40
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Aug 2020 18:08:04
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:08:04



US3412243

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:16

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Aug 2020 18:08:40
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 18:08:40
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Aug 2020 18:08:04
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:08:04

US3412243

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:16

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Aug 2020 18:08:40
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 18:08:40
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Aug 2020 18:08:04
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:08:04

US3412243

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:16

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Aug 2020 18:08:40
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 18:08:40
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Aug 2020 18:08:04
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 18:08:04

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:16

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:08:04

US3412243

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:16

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'LIVES IN HIGH RISK COUNTY'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:08:04

US3412243

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:16

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:08:04

US3412243

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:16

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:08:04

US3412243

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:16

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:08:04



US3412243

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:16

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'I'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:08:04

US3412243

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:16

**Resides in low density, multi-family setting without** (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:08:04

US3412243

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:16

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:08:04

US3412243

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:16

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:08:04

US3412243

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:34:16

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:39:40
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:08:04

US3412243

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:34:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'Yes (Y)'	Steven Anderson (b) (4)	14 Aug 2020 16:06:52

**US3412243**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:34:16**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '14 Aug 2020'	Steven Anderson (b) (4)	14 Aug 2020 16:06:52

US3412243

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:34:16

[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 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'Clinic (Clinic)'	Steven Anderson (b) (4)	14 Aug 2020 16:06:52



**US3412243**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:34:16**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User entered 'VISIT1'	System	14 Aug 2020 16:06:52

US3412243

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:34:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '14 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 16:04:27

US3412243

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:34:16

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	21 Aug 2020 04:31:37
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:31:37
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	14 Aug 2020 16:04:27
User entered '186359' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 16:04:27

US3412243

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:34:16

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 16:04:27

US3412243

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:34:16

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 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'No (N)'	Steven Anderson (b) (4)	14 Aug 2020 16:07:08

US3412243

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:34:16

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 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'No (N)'	Steven Anderson (b) (4)	14 Aug 2020 16:07:08

**US3412243**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 17:34:16**

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'No (N)'	Steven Anderson (b) (4)	14 Aug 2020 16:07:08

US3412243

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:34:16

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'Yes (Y)'	Steven Anderson (b) (4)	14 Aug 2020 16:07:08



**US3412243**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 17:34:16**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'No (N)'	Steven Anderson (b) (4)	14 Aug 2020 16:07:08

**US3412243**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 17:34:16**

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'No (N)'	Jacob sekinger (b) (4)	24 Sep 2020 13:40:31
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:20:56
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:16:54

US3412243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:34:16

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:10:55

US3412243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:34:16

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:10:55

**US3412243**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 17:34:16**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:10:55

US3412243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:34:16

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:10:55

US3412243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User accepted default value 'Pre-Dose (PREDOSE)'		20 Aug 2020 18:10:55

US3412243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:10:55



US3412243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '14 Aug 2020'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:10:55

**US3412243**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:34:16**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '11:10'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:10:55

**US3412243**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:34:16**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User entered '14 Aug 2020 11:10'	System	20 Aug 2020 18:10:55

US3412243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '36.7' C	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:10:55

US3412243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:10:55

**US3412243**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:34:16**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:10:55

US3412243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '66'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:10:55

US3412243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User entered 'bpm'	System	20 Aug 2020 18:10:55



US3412243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '16'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:10:55

US3412243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User entered 'breaths/min'	System	20 Aug 2020 18:10:55

US3412243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '112'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:10:55

US3412243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User entered 'mmHg'	System	20 Aug 2020 18:10:55

US3412243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '82'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:10:55

**US3412243**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:34:16**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User entered 'mmHg'	System	20 Aug 2020 18:10:55

US3412243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:34:16

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:10:55

US3412243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:34:16

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:10:55



US3412243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User accepted default value 'Post-Dose (POSTDOSE)'		20 Aug 2020 18:10:55

US3412243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:10:55

US3412243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '14 Aug 2020'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:10:55

US3412243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 04:31:33
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'NA' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 18:12:06
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		20 Aug 2020 18:10:55
User entered '12:36'	(b) (4), (b) (6)	20 Aug 2020 18:10:55

**US3412243**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:34:16**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User entered '14 Aug 2020 12:36'	System	20 Aug 2020 18:10:55

US3412243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '96.8' F	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:10:55

US3412243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:10:55

US3412243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:10:55



US3412243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '62'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:10:55

US3412243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User entered 'bpm'	System	20 Aug 2020 18:10:55

US3412243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '18'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:10:55

US3412243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User entered 'breaths/min'	System	20 Aug 2020 18:10:55

US3412243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '112'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:10:55

US3412243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User entered 'mmHg'	System	20 Aug 2020 18:10:55

US3412243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '82'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:10:55

US3412243

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User entered 'mmHg'	System	20 Aug 2020 18:10:55



US3412243

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:11:09

**US3412243**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:34:16**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:11:09

US3412243

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:34:16

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'Yes (Y)'	Steven Anderson (b) (4)	14 Aug 2020 16:10:01

US3412243

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:34:16

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered empty.	Steven Anderson (b) (4)	14 Aug 2020 16:10:01

US3412243

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:34:16

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 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered empty.	Steven Anderson (b) (4)	14 Aug 2020 16:10:01

US3412243

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:34:16

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User entered 'MRNA-1273 OR PLACEBO'	System	14 Aug 2020 16:10:01

US3412243

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:34:16

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '14 Aug 2020'	Steven Anderson (b) (4)	14 Aug 2020 16:10:01

US3412243

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:34:16

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '12:05'	Steven Anderson (b) (4)	14 Aug 2020 16:10:01



**US3412243**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:34:16**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User entered '14 Aug 2020 12:05'	System	14 Aug 2020 16:10:01

US3412243

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:34:16

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'Left Arm (LEFT ARM)'	Steven Anderson (b) (4)	14 Aug 2020 16:10:01

US3412243

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:34:16

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User entered 'ONCE'	System	14 Aug 2020 16:10:01

US3412243

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:34:16

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User entered 'INTRAMUSCULAR'	System	14 Aug 2020 16:10:01

US3412243

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:11:33

US3412243

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:16

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '14 Aug 2020'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:11:33

**US3412243**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:34:16**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '11:40'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:11:33

**US3412243**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:34:16**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User entered '14 Aug 2020 11:40'	System	20 Aug 2020 18:11:33



US3412243

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:34:16

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '14 Aug 2020'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:11:47

**US3412243**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:34:16**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		20 Aug 2020 18:11:47

US3412243

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:34:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:11:47

**US3412243**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:34:16**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '11:43'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:11:47

**US3412243**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:34:16**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User entered '14 Aug 2020 11:43'	System	20 Aug 2020 18:11:47

US3412243

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:34:16

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		20 Aug 2020 18:11:47

US3412243

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:34:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:11:47

**US3412243**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:34:16**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:11:47



**US3412243**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:34:16**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User entered empty.	System	20 Aug 2020 18:11:47

**US3412243**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:34:16**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:11:51

**US3412243**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:34:16**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User entered 'I'	System	20 Aug 2020 18:11:51

US3412243

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
Data entry locked.	System	14 Aug 2020 16:10:01
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 16:10:01

US3412243

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:34:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-14T12:42:47', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'f7ea86dd-47e5-4705-bdaa-4f7c12e8a774' User entered 'Yes (Y)'	System	14 Aug 2020 16:43:29
	System	14 Aug 2020 16:43:29

US3412243

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:34:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-14T12:42:59', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'f7ea86dd-47e5-4705-bdaa-4f7c12e8a774'	System	14 Aug 2020 16:43:29
User entered '96.8'	System	14 Aug 2020 16:43:29

US3412243

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:34:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-14T12:43:12', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'f7ea86dd-47e5-4705-bdaa-4f7c12e8a774' User entered 'No (N)'	System	14 Aug 2020 16:43:29
	System	14 Aug 2020 16:43:29

US3412243

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:34:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-14T12:43:25', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'f7ea86dd-47e5-4705-bdaa-4f7c12e8a774'	System	14 Aug 2020 16:43:29
User entered '14 Aug 2020 12:43'	System	14 Aug 2020 16:43:29



US3412243

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:34:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '14 Aug 2020 12:25'	System	14 Aug 2020 16:10:01

US3412243

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:34:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '14 Aug 2020 14:55'	System	14 Aug 2020 16:10:01

US3412243

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
Data entry locked.	System	14 Aug 2020 16:10:01
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 16:10:01

US3412243

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:34:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-14T18:57:55', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'ba0d9a15-55c3-4cec-9446-2b3c5a86ec49'	System	14 Aug 2020 22:58:24
User entered 'Yes (Y)'	System	14 Aug 2020 22:58:24

US3412243

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:34:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-14T18:58:06', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'ba0d9a15-55c3-4cec-9446-2b3c5a86ec49'	System	14 Aug 2020 22:58:24
User entered '98.6'	System	14 Aug 2020 22:58:24

US3412243

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:34:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-14T18:58:12', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'ba0d9a15-55c3-4cec-9446-2b3c5a86ec49'	System	14 Aug 2020 22:58:24
User entered 'No (N)'	System	14 Aug 2020 22:58:24

US3412243

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:34:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-14T18:58:20', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'ba0d9a15-55c3-4cec-9446-2b3c5a86ec49' User entered '14 Aug 2020 18:58'	System	14 Aug 2020 22:58:24
	System	14 Aug 2020 22:58:24

US3412243

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:34:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '14 Aug 2020 15:50'	System	14 Aug 2020 16:10:01



US3412243

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:34:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 16:10:01

US3412243

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
Data entry locked.	System	14 Aug 2020 16:10:01
User entered 'Day 2'	System	14 Aug 2020 16:10:01

US3412243

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:34:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-15T19:00:16', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'eb9e9189-8433-494c-bce6-274b636667ce' User entered 'Yes (Y)'	System	15 Aug 2020 23:00:41
	System	15 Aug 2020 23:00:41

US3412243

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:34:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-15T19:00:27', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'eb9e9189-8433-494c-bce6-274b636667ce' User entered '97.7'	System	15 Aug 2020 23:00:41
	System	15 Aug 2020 23:00:41

US3412243

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:34:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-15T19:00:34', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'eb9e9189-8433-494c-bce6-274b636667ce' User entered 'No (N)'	System	15 Aug 2020 23:00:41
	System	15 Aug 2020 23:00:41

US3412243

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:34:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-15T19:00:39', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'eb9e9189-8433-494c-bce6-274b636667ce' User entered '15 Aug 2020 19:00'	System	15 Aug 2020 23:00:41
	System	15 Aug 2020 23:00:41

US3412243

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:34:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 16:10:01

US3412243

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:34:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 16:10:01



US3412243

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
Data entry locked.	System	14 Aug 2020 16:10:01
User entered 'Day 3'	System	14 Aug 2020 16:10:01

US3412243

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:34:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-16T19:06:35', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'aad12be8-6ed9-4158-aa00-0c251a3da81c' User entered 'Yes (Y)'	System	16 Aug 2020 23:07:01
	System	16 Aug 2020 23:07:01

US3412243

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:34:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-16T19:06:46', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'aad12be8-6ed9-4158-aa00-0c251a3da81c' User entered '97.4'	System	16 Aug 2020 23:07:01
	System	16 Aug 2020 23:07:01

US3412243

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:34:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-16T19:06:53', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'aad12be8-6ed9-4158-aa00-0c251a3da81c' User entered 'No (N)'	System	16 Aug 2020 23:07:01
	System	16 Aug 2020 23:07:01

US3412243

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:34:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-16T19:06:58', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'aad12be8-6ed9-4158-aa00-0c251a3da81c' User entered '16 Aug 2020 19:06'	System	16 Aug 2020 23:07:01
	System	16 Aug 2020 23:07:01

US3412243

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:34:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 16:10:01

US3412243

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:34:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 16:10:01

US3412243

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
Data entry locked.	System	14 Aug 2020 16:10:01
User entered 'Day 4'	System	14 Aug 2020 16:10:01



US3412243

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:34:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-17T19:57:36', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '85066ee6-5e63-4312-844a-db2eacb80281' User entered 'Yes (Y)'	System	17 Aug 2020 23:58:11
	System	17 Aug 2020 23:58:11

US3412243

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:34:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-17T19:57:52', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '85066ee6-5e63-4312-844a-db2eacb80281' User entered '98.3'	System	17 Aug 2020 23:58:11
	System	17 Aug 2020 23:58:11

US3412243

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:34:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-17T19:58:00', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '85066ee6-5e63-4312-844a-db2eacb80281' User entered 'No (N)'	System	17 Aug 2020 23:58:11
	System	17 Aug 2020 23:58:11

US3412243

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:34:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-17T19:58:10', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '85066ee6-5e63-4312-844a-db2eacb80281' User entered '17 Aug 2020 19:58'	System	17 Aug 2020 23:58:11
	System	17 Aug 2020 23:58:11

US3412243

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:34:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 16:10:01

US3412243

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:34:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 16:10:01

US3412243

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
Data entry locked.	System	14 Aug 2020 16:10:01
User entered 'Day 5'	System	14 Aug 2020 16:10:01

US3412243

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:34:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-18T18:17:34', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '8d543049-4457-4cee-9a9d-b90159ba42a6' User entered 'Yes (Y)'	System	18 Aug 2020 22:17:59
	System	18 Aug 2020 22:17:59



US3412243

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:34:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-18T18:17:44', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '8d543049-4457-4cee-9a9d-b90159ba42a6' User entered '97.4'	System	18 Aug 2020 22:17:59
	System	18 Aug 2020 22:17:59

US3412243

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:34:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-18T18:17:51', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '8d543049-4457-4cee-9a9d-b90159ba42a6' User entered 'No (N)'	System	18 Aug 2020 22:17:59
	System	18 Aug 2020 22:17:59

US3412243

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:34:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-18T18:17:54', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '8d543049-4457-4cee-9a9d-b90159ba42a6' User entered '18 Aug 2020 18:17'	System	18 Aug 2020 22:17:59
	System	18 Aug 2020 22:17:59

US3412243

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:34:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 16:10:01

US3412243

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:34:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 16:10:01

US3412243

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
Data entry locked.	System	14 Aug 2020 16:10:01
User entered 'Day 6'	System	14 Aug 2020 16:10:01

US3412243

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:34:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-19T18:59:28', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'dd0c2c7d-ea6e-4fd1-9258-d0851e348311' User entered 'Yes (Y)'	System	19 Aug 2020 22:59:53
	System	19 Aug 2020 22:59:53

US3412243

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:34:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-19T18:59:36', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'dd0c2c7d-ea6e-4fd1-9258-d0851e348311' User entered '94.8'	System	19 Aug 2020 22:59:53
	System	19 Aug 2020 22:59:53



US3412243

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:34:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-19T18:59:43', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'dd0c2c7d-ea6e-4fd1-9258-d0851e348311' User entered 'No (N)'	System	19 Aug 2020 22:59:53
	System	19 Aug 2020 22:59:53

US3412243

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:34:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-19T18:59:47', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'dd0c2c7d-ea6e-4fd1-9258-d0851e348311' User entered '19 Aug 2020 18:59'	System	19 Aug 2020 22:59:53
	System	19 Aug 2020 22:59:53

US3412243

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:34:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 16:10:01

US3412243

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:34:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 16:10:01

US3412243

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
Data entry locked.	System	14 Aug 2020 16:10:01
User entered 'Day 7'	System	14 Aug 2020 16:10:01

US3412243

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:34:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-20T21:45:34', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '9aad0029-3993-4120-87e4-b41ac47cdc42'	System	21 Aug 2020 01:46:06
User entered 'Yes (Y)'	System	21 Aug 2020 01:46:06

US3412243

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:34:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-20T21:45:49', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '9aad0029-3993-4120-87e4-b41ac47cdc42'	System	21 Aug 2020 01:46:06
User entered '94.5'	System	21 Aug 2020 01:46:06

US3412243

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:34:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-20T21:46:00', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '9aad0029-3993-4120-87e4-b41ac47cdc42'	System	21 Aug 2020 01:46:06
User entered 'No (N)'	System	21 Aug 2020 01:46:06



US3412243

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:34:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-20T21:46:04', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '9aad0029-3993-4120-87e4-b41ac47cdc42'	System	21 Aug 2020 01:46:06
User entered '20 Aug 2020 21:46'	System	21 Aug 2020 01:46:06

US3412243

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:34:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 16:10:01

US3412243

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:34:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 16:10:01

US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
Data entry locked.	System	14 Aug 2020 16:10:01
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 16:10:01

US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:34:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-14T12:44:50', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '34311414-4c12-4244-8c60-902aa6915a15' User entered 'None (1)'	System	14 Aug 2020 16:45:34
	System	14 Aug 2020 16:45:34

US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:34:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-14T12:44:57', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '34311414-4c12-4244-8c60-902aa6915a15' User entered 'Yes (Y)'	System	14 Aug 2020 16:45:34
	System	14 Aug 2020 16:45:34

US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:34:16

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-14T12:45:06', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '34311414-4c12-4244-8c60-902aa6915a15' User entered '4'	System	14 Aug 2020 16:45:34
	System	14 Aug 2020 16:45:34

US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:34:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-14T12:45:15', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '34311414-4c12-4244-8c60-902aa6915a15' User entered 'No (N)'	System	14 Aug 2020 16:45:34
	System	14 Aug 2020 16:45:34



US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:34:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-14T12:45:22', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '34311414-4c12-4244-8c60-902aa6915a15' User entered 'None (1)'	System	14 Aug 2020 16:45:34
	System	14 Aug 2020 16:45:34

US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:34:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-14T12:45:30', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '34311414-4c12-4244-8c60-902aa6915a15' User entered '14 Aug 2020 12:45'	System	14 Aug 2020 16:45:34
	System	14 Aug 2020 16:45:34

US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:34:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '14 Aug 2020 12:25'	System	14 Aug 2020 16:10:01

US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:34:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '14 Aug 2020 14:55'	System	14 Aug 2020 16:10:01

US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
Data entry locked.	System	14 Aug 2020 16:10:01
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 16:10:01

US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:34:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-14T18:58:40', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '176ce760-8789-4e54-9e3a-268bebc5c2a3' User entered 'None (1)'	System	14 Aug 2020 22:59:03
	System	14 Aug 2020 22:59:03

US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:34:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-14T18:58:44', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '176ce760-8789-4e54-9e3a-268bebc5c2a3'	System	14 Aug 2020 22:59:03
User entered 'No (N)'	System	14 Aug 2020 22:59:03

US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:34:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-14T18:58:48', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '176ce760-8789-4e54-9e3a-268bebc5c2a3' User entered 'No (N)'	System	14 Aug 2020 22:59:03
	System	14 Aug 2020 22:59:03



US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:34:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-14T18:58:53', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '176ce760-8789-4e54-9e3a-268bebc5c2a3' User entered 'None (1)'	System	14 Aug 2020 22:59:03
	System	14 Aug 2020 22:59:03

US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:34:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-14T18:59:01', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '176ce760-8789-4e54-9e3a-268bebc5c2a3' User entered '14 Aug 2020 18:59'	System	14 Aug 2020 22:59:03
	System	14 Aug 2020 22:59:03

US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:34:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '14 Aug 2020 15:50'	System	14 Aug 2020 16:10:01

US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:34:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 16:10:01

US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
Data entry locked.	System	14 Aug 2020 16:10:01
User entered 'Day 2'	System	14 Aug 2020 16:10:01

US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:34:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-15T19:01:37', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '203f80ec-b852-48d9-a2b0-263b036744d6' User entered 'None (1)'	System	15 Aug 2020 23:01:54
	System	15 Aug 2020 23:01:54

US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:34:16

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-15T19:01:41', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '203f80ec-b852-48d9-a2b0-263b036744d6' User entered 'No (N)'	System	15 Aug 2020 23:01:54
	System	15 Aug 2020 23:01:54

US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:34:16

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-15T19:01:44', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '203f80ec-b852-48d9-a2b0-263b036744d6' User entered 'No (N)'	System	15 Aug 2020 23:01:54
	System	15 Aug 2020 23:01:54



US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:34:16

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-15T19:01:48', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '203f80ec-b852-48d9-a2b0-263b036744d6' User entered 'None (1)'	System	15 Aug 2020 23:01:54
	System	15 Aug 2020 23:01:54

US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:34:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-15T19:01:53', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '203f80ec-b852-48d9-a2b0-263b036744d6' User entered '15 Aug 2020 19:01'	System	15 Aug 2020 23:01:54
	System	15 Aug 2020 23:01:54

US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:34:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 16:10:01

US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:34:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 16:10:01

US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
Data entry locked.	System	14 Aug 2020 16:10:01
User entered 'Day 3'	System	14 Aug 2020 16:10:01

US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:34:16

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-16T19:07:07', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '074e0275-2ba0-41d0-a3c2-cc754eedfceb' User entered 'None (1)'	System	16 Aug 2020 23:07:28
	System	16 Aug 2020 23:07:28

US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:34:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-16T19:07:15', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '074e0275-2ba0-41d0-a3c2-cc754eedfceb' User entered 'No (N)'	System	16 Aug 2020 23:07:28
	System	16 Aug 2020 23:07:28

US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:34:16

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-16T19:07:18', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '074e0275-2ba0-41d0-a3c2-cc754eedfceb' User entered 'No (N)'	System	16 Aug 2020 23:07:28
	System	16 Aug 2020 23:07:28



US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:34:16

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-16T19:07:23', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '074e0275-2ba0-41d0-a3c2-cc754eedfceb' User entered 'None (1)'	System	16 Aug 2020 23:07:28
	System	16 Aug 2020 23:07:28

US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:34:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-16T19:07:26', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '074e0275-2ba0-41d0-a3c2-cc754eedfceb' User entered '16 Aug 2020 19:07'	System	16 Aug 2020 23:07:28
	System	16 Aug 2020 23:07:28

US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:34:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 16:10:01

US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:34:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 16:10:01

US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
Data entry locked.	System	14 Aug 2020 16:10:01
User entered 'Day 4'	System	14 Aug 2020 16:10:01

US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:34:16

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-17T19:58:21', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '3b43f6ff-82d9-40ee-9e00-7746de610472' User entered 'None (1)'	System	17 Aug 2020 23:58:42
	System	17 Aug 2020 23:58:42

US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:34:16

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-17T19:58:27', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '3b43f6ff-82d9-40ee-9e00-7746de610472'	System	17 Aug 2020 23:58:42
User entered 'No (N)'	System	17 Aug 2020 23:58:42

US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:34:16

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-17T19:58:30', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '3b43f6ff-82d9-40ee-9e00-7746de610472'	System	17 Aug 2020 23:58:42
User entered 'No (N)'	System	17 Aug 2020 23:58:42



US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:34:16

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-17T19:58:35', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '3b43f6ff-82d9-40ee-9e00-7746de610472' User entered 'None (1)'	System	17 Aug 2020 23:58:42
	System	17 Aug 2020 23:58:42

US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:34:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-17T19:58:39', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '3b43f6ff-82d9-40ee-9e00-7746de610472'	System	17 Aug 2020 23:58:42
User entered '17 Aug 2020 19:58'	System	17 Aug 2020 23:58:42

US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:34:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 16:10:01

US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:34:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 16:10:01

US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
Data entry locked.	System	14 Aug 2020 16:10:01
User entered 'Day 5'	System	14 Aug 2020 16:10:01

US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:34:16

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-18T18:18:00', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '0a2a36ba-307e-41e6-8c0d-201cdbc6a706' User entered 'None (1)'	System	18 Aug 2020 22:18:17
	System	18 Aug 2020 22:18:17

US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:34:16

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-18T18:18:04', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '0a2a36ba-307e-41e6-8c0d-201cdbc6a706' User entered 'No (N)'	System	18 Aug 2020 22:18:17
	System	18 Aug 2020 22:18:17

US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:34:16

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-18T18:18:08', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '0a2a36ba-307e-41e6-8c0d-201cdbc6a706' User entered 'No (N)'	System	18 Aug 2020 22:18:17
	System	18 Aug 2020 22:18:17



US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:34:16

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-18T18:18:11', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '0a2a36ba-307e-41e6-8c0d-201cdbc6a706' User entered 'None (1)'	System	18 Aug 2020 22:18:17
	System	18 Aug 2020 22:18:17

US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:34:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-18T18:18:15', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '0a2a36ba-307e-41e6-8c0d-201cdbc6a706' User entered '18 Aug 2020 18:18'	System	18 Aug 2020 22:18:17
	System	18 Aug 2020 22:18:17

US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:34:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 16:10:01

US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:34:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 16:10:01

US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
Data entry locked.	System	14 Aug 2020 16:10:01
User entered 'Day 6'	System	14 Aug 2020 16:10:01

US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:34:16

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-19T18:59:52', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'cb4f8383-9558-4738-8e10-2283346ecb20' User entered 'None (1)'	System	19 Aug 2020 23:00:09
	System	19 Aug 2020 23:00:09

US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:34:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-19T18:59:56', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'cb4f8383-9558-4738-8e10-2283346ecb20'	System	19 Aug 2020 23:00:09
User entered 'No (N)'	System	19 Aug 2020 23:00:09

US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:34:16

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-19T18:59:59', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'cb4f8383-9558-4738-8e10-2283346ecb20' User entered 'No (N)'	System	19 Aug 2020 23:00:09
	System	19 Aug 2020 23:00:09



US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:34:16

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-19T19:00:02', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'cb4f8383-9558-4738-8e10-2283346ecb20' User entered 'None (1)'	System	19 Aug 2020 23:00:09
	System	19 Aug 2020 23:00:09

US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:34:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-19T19:00:05', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'cb4f8383-9558-4738-8e10-2283346ecb20'	System	19 Aug 2020 23:00:09
User entered '19 Aug 2020 19:00'	System	19 Aug 2020 23:00:09

US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:34:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 16:10:01

US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:34:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 16:10:01

US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
Data entry locked.	System	14 Aug 2020 16:10:01
User entered 'Day 7'	System	14 Aug 2020 16:10:01

US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:34:16

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-20T21:46:09', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'dd5fa7db-e74b-45cb-84ea-9c39ccc9a414' User entered 'None (1)'	System	21 Aug 2020 01:46:27
	System	21 Aug 2020 01:46:27

US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:34:16

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-20T21:46:12', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'dd5fa7db-e74b-45cb-84ea-9c39ccc9a414' User entered 'No (N)'	System	21 Aug 2020 01:46:27
	System	21 Aug 2020 01:46:27

US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:34:16

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-20T21:46:16', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'dd5fa7db-e74b-45cb-84ea-9c39ccc9a414' User entered 'No (N)'	System	21 Aug 2020 01:46:27
	System	21 Aug 2020 01:46:27



US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:34:16

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-20T21:46:19', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'dd5fa7db-e74b-45cb-84ea-9c39ccc9a414' User entered 'None (1)'	System	21 Aug 2020 01:46:27
	System	21 Aug 2020 01:46:27

US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:34:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-20T21:46:22', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'dd5fa7db-e74b-45cb-84ea-9c39ccc9a414' User entered '20 Aug 2020 21:46'	System	21 Aug 2020 01:46:27
	System	21 Aug 2020 01:46:27

US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:34:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 16:10:01

US3412243

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:34:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 16:10:01

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
Data entry locked.	System	14 Aug 2020 16:10:01
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 16:10:01

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:16

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-14T12:45:43', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'de320935-2fa2-4068-9b0a-ebebed37eb29' User entered 'None (0)'	System	14 Aug 2020 16:46:33
	System	14 Aug 2020 16:46:33

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:16

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-14T12:45:47', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'de320935-2fa2-4068-9b0a-ebebed37eb29' User entered 'None (0)'	System	14 Aug 2020 16:46:33
	System	14 Aug 2020 16:46:33

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:16

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-14T12:45:51', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'de320935-2fa2-4068-9b0a-ebebed37eb29'	System	14 Aug 2020 16:46:33
User entered 'None (0)'	System	14 Aug 2020 16:46:33



US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:16

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-14T12:45:56', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'de320935-2fa2-4068-9b0a-ebebed37eb29' User entered 'None (0)'	System	14 Aug 2020 16:46:33
	System	14 Aug 2020 16:46:33

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:16

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-14T12:46:00', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'de320935-2fa2-4068-9b0a-ebebed37eb29' User entered 'None (0)'	System	14 Aug 2020 16:46:33
	System	14 Aug 2020 16:46:33

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:16

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-14T12:46:02', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'de320935-2fa2-4068-9b0a-ebebed37eb29'	System	14 Aug 2020 16:46:33
User entered 'None (0)'	System	14 Aug 2020 16:46:33

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:16

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-14T12:46:17', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'de320935-2fa2-4068-9b0a-ebebed37eb29' User entered 'No (N)'	System	14 Aug 2020 16:46:33
	System	14 Aug 2020 16:46:33

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-14T12:46:25', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'de320935-2fa2-4068-9b0a-ebebed37eb29'	System	14 Aug 2020 16:46:33
User entered '14 Aug 2020 12:46'	System	14 Aug 2020 16:46:33

**US3412243**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:34:16**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '14 Aug 2020 12:25'	System	14 Aug 2020 16:10:01

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '14 Aug 2020 14:55'	System	14 Aug 2020 16:10:01

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
Data entry locked.	System	14 Aug 2020 16:10:01
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 16:10:01



US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:16

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-14T18:59:21', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '439b1f5f-4514-4726-8e28-972e6c4a428c' User entered 'None (0)'	System	14 Aug 2020 22:59:55
	System	14 Aug 2020 22:59:55

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:16

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-14T18:59:26', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '439b1f5f-4514-4726-8e28-972e6c4a428c' User entered 'None (0)'	System	14 Aug 2020 22:59:55
	System	14 Aug 2020 22:59:55

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:16

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-14T18:59:30', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '439b1f5f-4514-4726-8e28-972e6c4a428c' User entered 'None (0)'	System	14 Aug 2020 22:59:55
	System	14 Aug 2020 22:59:55

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:16

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-14T18:59:33', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '439b1f5f-4514-4726-8e28-972e6c4a428c' User entered 'None (0)'	System	14 Aug 2020 22:59:55
	System	14 Aug 2020 22:59:55

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:16

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-14T18:59:36', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '439b1f5f-4514-4726-8e28-972e6c4a428c' User entered 'None (0)'	System	14 Aug 2020 22:59:55
	System	14 Aug 2020 22:59:55

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:16

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-14T18:59:38', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '439b1f5f-4514-4726-8e28-972e6c4a428c' User entered 'None (0)'	System	14 Aug 2020 22:59:55
	System	14 Aug 2020 22:59:55

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:16

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-14T18:59:45', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '439b1f5f-4514-4726-8e28-972e6c4a428c' User entered 'No (N)'	System	14 Aug 2020 22:59:55
	System	14 Aug 2020 22:59:55

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-14T18:59:52', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '439b1f5f-4514-4726-8e28-972e6c4a428c' User entered '14 Aug 2020 18:59'	System	14 Aug 2020 22:59:55
	System	14 Aug 2020 22:59:55



US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '14 Aug 2020 15:50'	System	14 Aug 2020 16:10:01

**US3412243**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:34:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 16:10:01

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
Data entry locked.	System	14 Aug 2020 16:10:01
User entered 'Day 2'	System	14 Aug 2020 16:10:01

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:16

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-15T19:00:54', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '096cada9-6d99-4d96-b60a-d7bd5ebfb87f' User entered 'None (0)'	System	15 Aug 2020 23:01:23
	System	15 Aug 2020 23:01:23

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:16

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-15T19:00:58', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '096cada9-6d99-4d96-b60a-d7bd5ebfb87f' User entered 'None (0)'	System	15 Aug 2020 23:01:23
	System	15 Aug 2020 23:01:23

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:16

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-15T19:01:03', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '096cada9-6d99-4d96-b60a-d7bd5ebfb87f' User entered 'None (0)'	System	15 Aug 2020 23:01:23
	System	15 Aug 2020 23:01:23

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:16

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-15T19:01:05', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '096cada9-6d99-4d96-b60a-d7bd5ebfb87f' User entered 'None (0)'	System	15 Aug 2020 23:01:23
	System	15 Aug 2020 23:01:23

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:16

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-15T19:01:08', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '096cada9-6d99-4d96-b60a-d7bd5ebfb87f' User entered 'None (0)'	System	15 Aug 2020 23:01:23
	System	15 Aug 2020 23:01:23



US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:16

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-15T19:01:11', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '096cada9-6d99-4d96-b60a-d7bd5ebfb87f' User entered 'None (0)'	System	15 Aug 2020 23:01:23
	System	15 Aug 2020 23:01:23

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:16

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-15T19:01:17', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '096cada9-6d99-4d96-b60a-d7bd5ebfb87f' User entered 'No (N)'	System	15 Aug 2020 23:01:23
	System	15 Aug 2020 23:01:23

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-15T19:01:22', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '096cada9-6d99-4d96-b60a-d7bd5ebfb87f' User entered '15 Aug 2020 19:01'	System	15 Aug 2020 23:01:23
	System	15 Aug 2020 23:01:23

**US3412243**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:34:16**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 16:10:01

**US3412243**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:34:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 16:10:01

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
Data entry locked.	System	14 Aug 2020 16:10:01
User entered 'Day 3'	System	14 Aug 2020 16:10:01

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:16

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-16T19:07:36', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '7f28f5f2-c225-4965-9f47-8420221ea6e1' User entered 'None (0)'	System	16 Aug 2020 23:08:17
	System	16 Aug 2020 23:08:17

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:16

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-16T19:07:41', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '7f28f5f2-c225-4965-9f47-8420221ea6e1' User entered 'None (0)'	System	16 Aug 2020 23:08:17
	System	16 Aug 2020 23:08:17



US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:16

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-16T19:07:44', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '7f28f5f2-c225-4965-9f47-8420221ea6e1' User entered 'None (0)'	System	16 Aug 2020 23:08:17
	System	16 Aug 2020 23:08:17

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:16

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-16T19:07:49', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '7f28f5f2-c225-4965-9f47-8420221ea6e1' User entered 'None (0)'	System	16 Aug 2020 23:08:17
	System	16 Aug 2020 23:08:17

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:16

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-16T19:07:53', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '7f28f5f2-c225-4965-9f47-8420221ea6e1' User entered 'None (0)'	System	16 Aug 2020 23:08:17
	System	16 Aug 2020 23:08:17

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:16

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-16T19:07:56', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '7f28f5f2-c225-4965-9f47-8420221ea6e1' User entered 'None (0)'	System	16 Aug 2020 23:08:17
	System	16 Aug 2020 23:08:17

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:16

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-16T19:08:05', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '7f28f5f2-c225-4965-9f47-8420221ea6e1'	System	16 Aug 2020 23:08:17
User entered 'No (N)'	System	16 Aug 2020 23:08:17

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-16T19:08:14', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '7f28f5f2-c225-4965-9f47-8420221ea6e1' User entered '16 Aug 2020 19:08'	System	16 Aug 2020 23:08:17
	System	16 Aug 2020 23:08:17

**US3412243**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:34:16**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 16:10:01

**US3412243**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:34:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 16:10:01



US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
Data entry locked.	System	14 Aug 2020 16:10:01
User entered 'Day 4'	System	14 Aug 2020 16:10:01

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:16

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-17T19:58:45', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '2d55a075-0aad-40b6-a03e-54d4c280546c' User entered 'None (0)'	System	17 Aug 2020 23:59:16
	System	17 Aug 2020 23:59:16

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:16

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-17T19:58:48', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '2d55a075-0aad-40b6-a03e-54d4c280546c' User entered 'None (0)'	System	17 Aug 2020 23:59:16
	System	17 Aug 2020 23:59:16

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:16

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-17T19:58:54', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '2d55a075-0aad-40b6-a03e-54d4c280546c' User entered 'None (0)'	System	17 Aug 2020 23:59:16
	System	17 Aug 2020 23:59:16

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:16

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-17T19:58:58', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '2d55a075-0aad-40b6-a03e-54d4c280546c' User entered 'None (0)'	System	17 Aug 2020 23:59:16
	System	17 Aug 2020 23:59:16

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:16

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-17T19:59:01', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '2d55a075-0aad-40b6-a03e-54d4c280546c' User entered 'None (0)'	System	17 Aug 2020 23:59:16
	System	17 Aug 2020 23:59:16

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:16

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-17T19:59:04', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '2d55a075-0aad-40b6-a03e-54d4c280546c' User entered 'None (0)'	System	17 Aug 2020 23:59:16
	System	17 Aug 2020 23:59:16

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:16

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-17T19:59:11', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '2d55a075-0aad-40b6-a03e-54d4c280546c'	System	17 Aug 2020 23:59:16
User entered 'No (N)'	System	17 Aug 2020 23:59:16



US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-17T19:59:13', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '2d55a075-0aad-40b6-a03e-54d4c280546c' User entered '17 Aug 2020 19:59'	System	17 Aug 2020 23:59:16
	System	17 Aug 2020 23:59:16

**US3412243**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:34:16**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 16:10:01

**US3412243**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:34:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 16:10:01

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
Data entry locked.	System	14 Aug 2020 16:10:01
User entered 'Day 5'	System	14 Aug 2020 16:10:01

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:16

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-18T18:18:21', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '94e417a8-27a4-4e4e-845c-8ad5fd6755ee' User entered 'None (0)'	System	18 Aug 2020 22:18:51
	System	18 Aug 2020 22:18:51

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:16

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-18T18:18:24', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '94e417a8-27a4-4e4e-845c-8ad5fd6755ee' User entered 'None (0)'	System	18 Aug 2020 22:18:51
	System	18 Aug 2020 22:18:51

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:16

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-18T18:18:27', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '94e417a8-27a4-4e4e-845c-8ad5fd6755ee' User entered 'None (0)'	System	18 Aug 2020 22:18:51
	System	18 Aug 2020 22:18:51

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:16

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-18T18:18:29', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '94e417a8-27a4-4e4e-845c-8ad5fd6755ee' User entered 'None (0)'	System	18 Aug 2020 22:18:51
	System	18 Aug 2020 22:18:51



US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:16

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-18T18:18:35', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '94e417a8-27a4-4e4e-845c-8ad5fd6755ee' User entered 'None (0)'	System	18 Aug 2020 22:18:51
	System	18 Aug 2020 22:18:51

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:16

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-18T18:18:37', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '94e417a8-27a4-4e4e-845c-8ad5fd6755ee' User entered 'None (0)'	System	18 Aug 2020 22:18:51
	System	18 Aug 2020 22:18:51

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:16

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-18T18:18:44', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '94e417a8-27a4-4e4e-845c-8ad5fd6755ee' User entered 'No (N)'	System	18 Aug 2020 22:18:51
	System	18 Aug 2020 22:18:51

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-18T18:18:47', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '94e417a8-27a4-4e4e-845c-8ad5fd6755ee' User entered '18 Aug 2020 18:18'	System	18 Aug 2020 22:18:51
	System	18 Aug 2020 22:18:51

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 16:10:01

**US3412243**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:34:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 16:10:01

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
Data entry locked.	System	14 Aug 2020 16:10:01
User entered 'Day 6'	System	14 Aug 2020 16:10:01

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:16

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-19T19:00:12', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'e32a761f-cba9-4605-ac1b-0fb000d834c0' User entered 'None (0)'	System	19 Aug 2020 23:00:38
	System	19 Aug 2020 23:00:38



US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:16

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-19T19:00:15', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'e32a761f-cba9-4605-ac1b-0fb000d834c0' User entered 'None (0)'	System	19 Aug 2020 23:00:38
	System	19 Aug 2020 23:00:38

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:16

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-19T19:00:18', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'e32a761f-cba9-4605-ac1b-0fb000d834c0' User entered 'None (0)'	System	19 Aug 2020 23:00:38
	System	19 Aug 2020 23:00:38

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:16

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-19T19:00:21', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'e32a761f-cba9-4605-ac1b-0fb000d834c0' User entered 'None (0)'	System	19 Aug 2020 23:00:38
	System	19 Aug 2020 23:00:38

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:16

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-19T19:00:24', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'e32a761f-cba9-4605-ac1b-0fb000d834c0' User entered 'None (0)'	System	19 Aug 2020 23:00:38
	System	19 Aug 2020 23:00:38

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:16

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-19T19:00:26', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'e32a761f-cba9-4605-ac1b-0fb000d834c0' User entered 'None (0)'	System	19 Aug 2020 23:00:38
	System	19 Aug 2020 23:00:38

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:16

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-19T19:00:33', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'e32a761f-cba9-4605-ac1b-0fb000d834c0'	System	19 Aug 2020 23:00:38
User entered 'No (N)'	System	19 Aug 2020 23:00:38

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-19T19:00:36', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'e32a761f-cba9-4605-ac1b-0fb000d834c0' User entered '19 Aug 2020 19:00'	System	19 Aug 2020 23:00:38
	System	19 Aug 2020 23:00:38

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 16:10:01



US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 16:10:01

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
Data entry locked.	System	14 Aug 2020 16:10:01
User entered 'Day 7'	System	14 Aug 2020 16:10:01

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:16

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-20T21:46:27', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'd7ee0fd5-c165-4e11-a89f-aae4143710d5' User entered 'None (0)'	System	21 Aug 2020 01:46:53
	System	21 Aug 2020 01:46:53

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:16

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-20T21:46:30', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'd7ee0fd5-c165-4e11-a89f-aae4143710d5' User entered 'None (0)'	System	21 Aug 2020 01:46:53
	System	21 Aug 2020 01:46:53

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:16

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-20T21:46:33', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'd7ee0fd5-c165-4e11-a89f-aae4143710d5' User entered 'None (0)'	System	21 Aug 2020 01:46:53
	System	21 Aug 2020 01:46:53

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:16

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-20T21:46:35', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'd7ee0fd5-c165-4e11-a89f-aae4143710d5' User entered 'None (0)'	System	21 Aug 2020 01:46:53
	System	21 Aug 2020 01:46:53

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:16

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-20T21:46:37', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'd7ee0fd5-c165-4e11-a89f-aae4143710d5' User entered 'None (0)'	System	21 Aug 2020 01:46:53
	System	21 Aug 2020 01:46:53

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:16

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-20T21:46:39', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'd7ee0fd5-c165-4e11-a89f-aae4143710d5' User entered 'None (0)'	System	21 Aug 2020 01:46:53
	System	21 Aug 2020 01:46:53



US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:16

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-20T21:46:46', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'd7ee0fd5-c165-4e11-a89f-aae4143710d5'	System	21 Aug 2020 01:46:53
User entered 'No (N)'	System	21 Aug 2020 01:46:53

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-08-20T21:46:50', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'd7ee0fd5-c165-4e11-a89f-aae4143710d5' User entered '20 Aug 2020 21:46'	System	21 Aug 2020 01:46:53
	System	21 Aug 2020 01:46:53

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 16:10:01

US3412243

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 16:10:01

**US3412243**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:34:16**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:54:28

**US3412243**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:34:16**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '21 Aug 2020'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:54:28

**US3412243**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:34:16**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:54:28

US3412243

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:16

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:54:28



US3412243

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 20:54:36

**US3412243**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:34:16**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User entered 'I'	System	21 Aug 2020 20:54:36

**US3412243**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:34:16**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:01:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 20:02:03

**US3412243**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:34:16**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:01:51
User entered '28 Aug 2020'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 20:02:03

US3412243

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:01:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 20:02:03

**US3412243**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:34:16**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:01:51
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Aug 2020 20:02:03

**US3412243**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:34:16**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:01:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 20:02:08

**US3412243**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:34:16**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User entered 'I'	System	28 Aug 2020 20:02:08



**US3412243**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:34:16**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:01:51
User entered 'Yes (Y)'	Mason Urban (b) (4)	04 Sep 2020 14:06:53

**US3412243**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:34:16**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:01:51
User entered '4 Sep 2020'	Mason Urban (b) (4)	04 Sep 2020 14:06:53

US3412243

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:01:51
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	04 Sep 2020 14:06:53

**US3412243**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:34:16**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:01:51
User entered empty.	Mason Urban (b) (4)	04 Sep 2020 14:06:53

US3412243

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:01:51
User entered 'Yes (Y)'	Mason Urban (b) (4)	04 Sep 2020 14:06:59

US3412243

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User entered 'I'	System	04 Sep 2020 14:06:59

US3412243

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'Yes (Y)'	Steven Anderson (b) (4)	11 Sep 2020 15:00:28

US3412243

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:16

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '11 Sep 2020'	Steven Anderson (b) (4)	11 Sep 2020 15:00:28



US3412243

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:16

[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 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'Clinic (Clinic)'	Steven Anderson (b) (4)	11 Sep 2020 15:00:28

**US3412243**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:34:16**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User entered 'VISIT2'	System	11 Sep 2020 15:00:28

US3412243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User accepted default value 'Pre-Dose (PREDOSE)'	Steven Anderson (b) (4)	11 Sep 2020 15:01:13
	(b) (4)	

US3412243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:16

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'Yes (Y)'	Steven Anderson (b) (4)	11 Sep 2020 15:01:13

US3412243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '11 Sep 2020'	Steven Anderson (b) (4)	11 Sep 2020 15:01:13

**US3412243**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:34:16**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '10:37'	Steven Anderson (b) (4)	11 Sep 2020 15:01:13

US3412243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User entered '11 Sep 2020 10:37'	System	11 Sep 2020 15:01:13

US3412243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '36.8' C	Steven Anderson (b) (4)	11 Sep 2020 15:01:13



US3412243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'Oral (Oral)'	Steven Anderson (b) (4)	11 Sep 2020 15:01:13

**US3412243**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:34:16**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered empty.	Steven Anderson (b) (4)	11 Sep 2020 15:01:13

**US3412243**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:34:16**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '66'	Steven Anderson (b) (4)	11 Sep 2020 15:01:13

US3412243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User entered 'bpm'	System	11 Sep 2020 15:01:13

US3412243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '16'	Steven Anderson (b) (4)	11 Sep 2020 15:01:13

US3412243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User entered 'breaths/min'	System	11 Sep 2020 15:01:13

US3412243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:16

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '128'	Steven Anderson (b) (4)	11 Sep 2020 15:01:13

US3412243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User entered 'mmHg'	System	11 Sep 2020 15:01:13



US3412243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '88'	Steven Anderson (b) (4)	11 Sep 2020 15:01:13

US3412243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User entered 'mmHg'	System	11 Sep 2020 15:01:13

US3412243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User accepted default value 'Post-Dose (POSTDOSE)'	Steven Anderson (b) (4)	11 Sep 2020 15:01:13

US3412243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Sep 2020 19:59:17
User entered 'Yes (Y)' reason for change: Data Entry Error	System	14 Sep 2020 19:59:17
User opened query 'Data is required. Please complete.' (Site from System).	Steven Anderson (b) (4)	14 Sep 2020 19:59:17
User entered empty.	(b) (4)	
	System	11 Sep 2020 15:01:13
	Steven Anderson (b) (4)	11 Sep 2020 15:01:13
	(b) (4)	

US3412243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '11 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Steven Anderson (b) (4)	14 Sep 2020 19:59:17
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	11 Sep 2020 15:01:13
	(b) (4)	

US3412243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:16

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '12:03' reason for change: Data Entry Error	(b) (4)	
	Steven Anderson (b) (4)	14 Sep 2020 19:59:17
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	11 Sep 2020 15:01:13
	(b) (4)	

**US3412243**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:34:16**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User entered '11 Sep 2020 12:03'	System	14 Sep 2020 19:59:17
User entered empty.	System	11 Sep 2020 15:01:13

US3412243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User closed query "Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate." (Site from System).	(b) (4) (b) (4), (b) (6)	29 Sep 2020 13:03:12
Query "Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate." answered with 'temperature within normal range. ' (Site from System).	Jacob sekinger (b) (4) (b) (4)	24 Sep 2020 13:42:22
Amendment Manager: User opened query "Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate." (Site from System).	System	16 Sep 2020 23:57:08
User entered '96.7' F reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	14 Sep 2020 19:59:17
User entered empty.	Steven Anderson (b) (4) (b) (4)	11 Sep 2020 15:01:13



US3412243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	
	Steven Anderson (b) (4)	14 Sep 2020 19:59:17
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	11 Sep 2020 15:01:13
	(b) (4)	

US3412243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered empty.	Steven Anderson (b) (4)	11 Sep 2020 15:01:13

US3412243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '58' reason for change: Data Entry Error	(b) (4)	
	Steven Anderson (b) (4)	14 Sep 2020 19:59:17
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	11 Sep 2020 15:01:13
	(b) (4)	

US3412243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User entered 'bpm'	System	14 Sep 2020 19:59:17
User entered empty.	System	11 Sep 2020 15:01:13

US3412243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '16' reason for change: Data Entry Error	(b) (4)	
	Steven Anderson (b) (4)	14 Sep 2020 19:59:17
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	11 Sep 2020 15:01:13
	(b) (4)	

US3412243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User entered 'breaths/min'	System	14 Sep 2020 19:59:17
User entered empty.	System	11 Sep 2020 15:01:13

US3412243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '108' reason for change: Data Entry Error	(b) (4)	
	Steven Anderson (b) (4)	14 Sep 2020 19:59:17
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	11 Sep 2020 15:01:13
	(b) (4)	

US3412243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User entered 'mmHg'	System	14 Sep 2020 19:59:17
User entered empty.	System	11 Sep 2020 15:01:13



US3412243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '82' reason for change: Data Entry Error	(b) (4)	
	Steven Anderson (b) (4)	14 Sep 2020 19:59:17
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	11 Sep 2020 15:01:13
	(b) (4)	

US3412243

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User entered 'mmHg'	System	14 Sep 2020 19:59:17
User entered empty.	System	11 Sep 2020 15:01:13

US3412243

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'Yes (Y)'	Steven Anderson (b) (4)	11 Sep 2020 15:01:25

US3412243

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '11 Sep 2020'	Steven Anderson (b) (4)	11 Sep 2020 15:01:25

**US3412243**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:34:16**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'Yes (Y)'	Steven Anderson (b) (4)	11 Sep 2020 15:26:45

US3412243

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:16

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered empty.	Steven Anderson (b) (4)	11 Sep 2020 15:26:45

US3412243

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:16

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 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered empty.	Steven Anderson (b) (4)	11 Sep 2020 15:26:45

US3412243

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:16

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User entered 'MRNA-1273 OR PLACEBO'	System	11 Sep 2020 15:26:45



US3412243

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:16

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '11 Sep 2020'	Steven Anderson (b) (4)	11 Sep 2020 15:26:45

US3412243

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:16

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '11:25'	Steven Anderson (b) (4)	11 Sep 2020 15:26:45

US3412243

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:16

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User entered '11 Sep 2020 11:25'	System	11 Sep 2020 15:26:45

US3412243

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:16

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'Left Arm (LEFT ARM)'	Steven Anderson (b) (4)	11 Sep 2020 15:26:45

US3412243

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:16

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User entered 'ONCE'	System	11 Sep 2020 15:26:45

US3412243

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:16

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User entered 'INTRAMUSCULAR'	System	11 Sep 2020 15:26:45

US3412243

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'Yes (Y)'	Steven Anderson (b) (4)	11 Sep 2020 15:01:50

US3412243

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:16

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '11 Sep 2020'	Steven Anderson (b) (4)	11 Sep 2020 15:01:50



**US3412243**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:34:16**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '10:49'	Steven Anderson (b) (4)	11 Sep 2020 15:01:50

**US3412243**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:34:16**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User entered '11 Sep 2020 10:49'	System	11 Sep 2020 15:01:50

US3412243

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:34:16

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '11 Sep 2020'	Steven Anderson (b) (4)	11 Sep 2020 15:02:08

**US3412243**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:34:16**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Steven Anderson (b) (4)	11 Sep 2020 15:02:08

**US3412243**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:34:16**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'Yes (Y)'	Steven Anderson (b) (4)	11 Sep 2020 15:02:08

**US3412243**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:34:16**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '10:52'	Steven Anderson (b) (4)	11 Sep 2020 15:02:08

**US3412243**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:34:16**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User entered '11 Sep 2020 10:52'	System	11 Sep 2020 15:02:08

**US3412243**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:34:16**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Steven Anderson (b) (4)	11 Sep 2020 15:02:08



**US3412243**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:34:16**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'No (N)'	Steven Anderson (b) (4)	11 Sep 2020 15:02:08

**US3412243**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:34:16**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered empty.	Steven Anderson (b) (4)	11 Sep 2020 15:02:08

**US3412243**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:34:16**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User entered empty.	System	11 Sep 2020 15:02:08

US3412243

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'Yes (Y)'	Steven Anderson (b) (4)	11 Sep 2020 15:02:13

**US3412243**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:34:16**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User entered 'I'	System	11 Sep 2020 15:02:13

US3412243

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
Data entry locked.	System	11 Sep 2020 15:26:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 15:26:45

US3412243

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:34:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-11T12:08:01', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'b600b364-33a8-4fc4-a796-4eed8889a7b3' User entered 'Yes (Y)'	System	11 Sep 2020 16:09:05
	System	11 Sep 2020 16:09:05

US3412243

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:34:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-11T12:07:38', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'b600b364-33a8-4fc4-a796-4eed8889a7b3' User entered '96.7'	System	11 Sep 2020 16:09:05
	System	11 Sep 2020 16:09:05



US3412243

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:34:16

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-11T12:07:45', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'b600b364-33a8-4fc4-a796-4eed8889a7b3' User entered 'No (N)'	System	11 Sep 2020 16:09:05
	System	11 Sep 2020 16:09:05

US3412243

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:34:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-11T12:08:09', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'b600b364-33a8-4fc4-a796-4eed8889a7b3' User entered '11 Sep 2020 12:08'	System	11 Sep 2020 16:09:05
	System	11 Sep 2020 16:09:05

US3412243

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:34:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '11 Sep 2020 11:45'	System	11 Sep 2020 15:26:45

US3412243

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:34:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '11 Sep 2020 14:15'	System	11 Sep 2020 15:26:45

US3412243

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
Data entry locked.	System	11 Sep 2020 15:26:45
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 15:26:45

US3412243

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:34:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-11T18:49:56', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '76156a2b-dfc4-4880-b409-8156884539fb' User entered 'Yes (Y)'	System	11 Sep 2020 22:50:23
	System	11 Sep 2020 22:50:23

US3412243

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:34:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-11T18:49:42', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '76156a2b-dfc4-4880-b409-8156884539fb' User entered '97.3'	System	11 Sep 2020 22:50:23
	System	11 Sep 2020 22:50:23

US3412243

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:34:16

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-11T18:49:47', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '76156a2b-dfc4-4880-b409-8156884539fb' User entered 'No (N)'	System	11 Sep 2020 22:50:23
	System	11 Sep 2020 22:50:23



US3412243

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:34:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-11T18:50:04', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '76156a2b-dfc4-4880-b409-8156884539fb' User entered '11 Sep 2020 18:50'	System	11 Sep 2020 22:50:23
	System	11 Sep 2020 22:50:23

US3412243

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:34:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '11 Sep 2020 15:10'	System	11 Sep 2020 15:26:45

US3412243

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:34:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 15:26:45

US3412243

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
Data entry locked.	System	11 Sep 2020 15:26:45
User entered 'Day 2'	System	11 Sep 2020 15:26:45

US3412243

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:34:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-12T18:19:41', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'd90ac08f-ec08-4d28-b1b0-8986d947eef0' User entered 'Yes (Y)'	System	12 Sep 2020 22:20:06
	System	12 Sep 2020 22:20:06

US3412243

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:34:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-12T18:19:48', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'd90ac08f-ec08-4d28-b1b0-8986d947eef0' User entered '97.3'	System	12 Sep 2020 22:20:06
	System	12 Sep 2020 22:20:06

US3412243

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:34:16

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-12T18:19:57', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'd90ac08f-ec08-4d28-b1b0-8986d947eef0' User entered 'No (N)'	System	12 Sep 2020 22:20:06
	System	12 Sep 2020 22:20:06

US3412243

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:34:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-12T18:20:03', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'd90ac08f-ec08-4d28-b1b0-8986d947eef0' User entered '12 Sep 2020 18:20'	System	12 Sep 2020 22:20:06
	System	12 Sep 2020 22:20:06



US3412243

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:34:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 15:26:45

US3412243

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:34:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 15:26:45

US3412243

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
Data entry locked.	System	11 Sep 2020 15:26:45
User entered 'Day 3'	System	11 Sep 2020 15:26:45

US3412243

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:34:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-13T18:24:48', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'dff59263-de16-4494-94f4-8eba434ffd9a' User entered 'Yes (Y)'	System	13 Sep 2020 22:25:08
	System	13 Sep 2020 22:25:08

US3412243

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:34:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-13T18:24:54', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'dff59263-de16-4494-94f4-8eba434ffd9a' User entered '98.3'	System	13 Sep 2020 22:25:08
	System	13 Sep 2020 22:25:08

US3412243

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:34:16

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-13T18:25:01', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'dff59263-de16-4494-94f4-8eba434ffd9a' User entered 'No (N)'	System	13 Sep 2020 22:25:08
	System	13 Sep 2020 22:25:08

US3412243

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:34:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-13T18:25:05', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'dff59263-de16-4494-94f4-8eba434ffd9a'	System	13 Sep 2020 22:25:08
User entered '13 Sep 2020 18:25'	System	13 Sep 2020 22:25:08

US3412243

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:34:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 15:26:45



US3412243

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:34:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 15:26:45

US3412243

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
Data entry locked.	System	11 Sep 2020 15:26:45
User entered 'Day 4'	System	11 Sep 2020 15:26:45

US3412243

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:34:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-14T18:02:38', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '73851c6e-3438-4582-b0b0-30093dd84e89' User entered 'Yes (Y)'	System	14 Sep 2020 22:02:58
	System	14 Sep 2020 22:02:58

US3412243

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:34:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-14T18:02:46', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '73851c6e-3438-4582-b0b0-30093dd84e89' User entered '97.7'	System	14 Sep 2020 22:02:58
	System	14 Sep 2020 22:02:58

US3412243

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:34:16

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-14T18:02:50', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '73851c6e-3438-4582-b0b0-30093dd84e89' User entered 'No (N)'	System	14 Sep 2020 22:02:58
	System	14 Sep 2020 22:02:58

US3412243

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:34:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-14T18:02:53', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '73851c6e-3438-4582-b0b0-30093dd84e89'	System	14 Sep 2020 22:02:58
User entered '14 Sep 2020 18:02'	System	14 Sep 2020 22:02:58

US3412243

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:34:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 15:26:45

US3412243

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:34:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 15:26:45



US3412243

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
Data entry locked.	System	11 Sep 2020 15:26:45
User entered 'Day 5'	System	11 Sep 2020 15:26:45

US3412243

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:34:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-15T17:26:42', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '2aa87183-00cc-485b-8c88-af0f1e1e6442'	System	15 Sep 2020 21:27:00
User entered 'Yes (Y)'	System	15 Sep 2020 21:27:00

US3412243

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:34:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-15T17:26:48', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '2aa87183-00cc-485b-8c88-af0f1e1e6442'	System	15 Sep 2020 21:27:00
User entered '97.0'	System	15 Sep 2020 21:27:00

US3412243

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:34:16

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-15T17:26:53', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '2aa87183-00cc-485b-8c88-af0f1e1e6442'	System	15 Sep 2020 21:27:00
User entered 'No (N)'	System	15 Sep 2020 21:27:00

US3412243

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:34:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-15T17:26:57', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '2aa87183-00cc-485b-8c88-af0f1e1e6442'	System	15 Sep 2020 21:27:00
User entered '15 Sep 2020 17:26'	System	15 Sep 2020 21:27:00

US3412243

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:34:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 15:26:45

US3412243

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:34:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 15:26:45

US3412243

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
Data entry locked.	System	11 Sep 2020 15:26:45
User entered 'Day 6'	System	11 Sep 2020 15:26:45



US3412243

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:34:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-16T16:40:17', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '6cf150b6-4842-4afd-baff-9331bc219014' User entered 'Yes (Y)'	System	16 Sep 2020 20:40:39
	System	16 Sep 2020 20:40:39

US3412243

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:34:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-16T16:40:28', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '6cf150b6-4842-4afd-baff-9331bc219014' User entered '98.7'	System	16 Sep 2020 20:40:39
	System	16 Sep 2020 20:40:39

US3412243

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:34:16

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-16T16:40:34', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '6cf150b6-4842-4afd-baff-9331bc219014' User entered 'No (N)'	System	16 Sep 2020 20:40:39
	System	16 Sep 2020 20:40:39

US3412243

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:34:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-16T16:40:37', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '6cf150b6-4842-4afd-baff-9331bc219014'	System	16 Sep 2020 20:40:39
User entered '16 Sep 2020 16:40'	System	16 Sep 2020 20:40:39

US3412243

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:34:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 15:26:45

US3412243

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:34:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 15:26:45

US3412243

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
Data entry locked.	System	11 Sep 2020 15:26:45
User entered 'Day 7'	System	11 Sep 2020 15:26:45

US3412243

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:34:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-17T17:31:53', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'd0692be0-960d-4994-bfdc-944aaeb826ca' User entered 'Yes (Y)'	System	17 Sep 2020 21:32:38
	System	17 Sep 2020 21:32:38



US3412243

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:34:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-17T17:32:00', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'd0692be0-960d-4994-bfdc-944aaeb826ca' User entered '98.9'	System	17 Sep 2020 21:32:38
	System	17 Sep 2020 21:32:38

US3412243

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:34:16

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-17T17:32:08', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'd0692be0-960d-4994-bfdc-944aaeb826ca' User entered 'No (N)'	System	17 Sep 2020 21:32:38
	System	17 Sep 2020 21:32:38

US3412243

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:34:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-17T17:32:11', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'd0692be0-960d-4994-bfdc-944aaeb826ca' User entered '17 Sep 2020 17:32'	System	17 Sep 2020 21:32:38
	System	17 Sep 2020 21:32:38

US3412243

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:34:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 15:26:45

US3412243

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:34:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 15:26:45

US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
Data entry locked.	System	11 Sep 2020 15:26:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 15:26:45

US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:34:16

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-11T12:08:19', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '768e8872-f4e4-40fa-a808-d5babe1ef0f1' User entered 'None (1)'	System	11 Sep 2020 16:09:13
	System	11 Sep 2020 16:09:13

US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:34:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-11T12:08:25', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '768e8872-f4e4-40fa-a808-d5babe1ef0f1' User entered 'No (N)'	System	11 Sep 2020 16:09:13
	System	11 Sep 2020 16:09:13



US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:34:16

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-11T12:08:30', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '768e8872-f4e4-40fa-a808-d5babe1ef0f1' User entered 'No (N)'	System	11 Sep 2020 16:09:13
	System	11 Sep 2020 16:09:13

US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:34:16

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-11T12:08:34', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '768e8872-f4e4-40fa-a808-d5babe1ef0f1' User entered 'None (1)'	System	11 Sep 2020 16:09:13
	System	11 Sep 2020 16:09:13

US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:34:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-11T12:08:39', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '768e8872-f4e4-40fa-a808-d5babe1ef0f1' User entered '11 Sep 2020 12:08'	System	11 Sep 2020 16:09:13
	System	11 Sep 2020 16:09:13

US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:34:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '11 Sep 2020 11:45'	System	11 Sep 2020 15:26:45

US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:34:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '11 Sep 2020 14:15'	System	11 Sep 2020 15:26:45

US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
Data entry locked.	System	11 Sep 2020 15:26:45
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 15:26:45

US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:34:16

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-11T18:50:13', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '95381dbf-e679-4cd9-93a5-8cd9e13b0e79' User entered 'None (1)'	System	11 Sep 2020 22:50:31
	System	11 Sep 2020 22:50:31

US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:34:16

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-11T18:50:17', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '95381dbf-e679-4cd9-93a5-8cd9e13b0e79' User entered 'No (N)'	System	11 Sep 2020 22:50:31
	System	11 Sep 2020 22:50:31



US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:34:16

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-11T18:50:20', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '95381dbf-e679-4cd9-93a5-8cd9e13b0e79' User entered 'No (N)'	System	11 Sep 2020 22:50:31
	System	11 Sep 2020 22:50:31

US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:34:16

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-11T18:50:23', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '95381dbf-e679-4cd9-93a5-8cd9e13b0e79' User entered 'None (1)'	System	11 Sep 2020 22:50:31
	System	11 Sep 2020 22:50:31

US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:34:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-11T18:50:25', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '95381dbf-e679-4cd9-93a5-8cd9e13b0e79'	System	11 Sep 2020 22:50:31
User entered '11 Sep 2020 18:50'	System	11 Sep 2020 22:50:31

US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:34:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '11 Sep 2020 15:10'	System	11 Sep 2020 15:26:45

US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:34:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 15:26:45

US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
Data entry locked.	System	11 Sep 2020 15:26:45
User entered 'Day 2'	System	11 Sep 2020 15:26:45

US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:34:16

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-12T18:20:08', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'd8897505-49a3-4c7d-be16-5a42b71c51d8' User entered 'None (1)'	System	12 Sep 2020 22:20:24
	System	12 Sep 2020 22:20:24

US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:34:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-12T18:20:13', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'd8897505-49a3-4c7d-be16-5a42b71c51d8' User entered 'No (N)'	System	12 Sep 2020 22:20:24
	System	12 Sep 2020 22:20:24



US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:34:16

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-12T18:20:16', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'd8897505-49a3-4c7d-be16-5a42b71c51d8' User entered 'No (N)'	System	12 Sep 2020 22:20:24
	System	12 Sep 2020 22:20:24

US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:34:16

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-12T18:20:19', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'd8897505-49a3-4c7d-be16-5a42b71c51d8'	System	12 Sep 2020 22:20:24
User entered 'None (1)'	System	12 Sep 2020 22:20:24

US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:34:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-12T18:20:22', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'd8897505-49a3-4c7d-be16-5a42b71c51d8'	System	12 Sep 2020 22:20:24
User entered '12 Sep 2020 18:20'	System	12 Sep 2020 22:20:24

US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:34:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 15:26:45

US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:34:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 15:26:45

US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
Data entry locked.	System	11 Sep 2020 15:26:45
User entered 'Day 3'	System	11 Sep 2020 15:26:45

US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:34:16

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-13T18:25:10', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '931468c4-65cb-443a-9a23-bff650e487f0' User entered 'None (1)'	System	13 Sep 2020 22:25:25
	System	13 Sep 2020 22:25:25

US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:34:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-13T18:25:14', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '931468c4-65cb-443a-9a23-bff650e487f0' User entered 'No (N)'	System	13 Sep 2020 22:25:25
	System	13 Sep 2020 22:25:25



US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:34:16

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-13T18:25:17', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '931468c4-65cb-443a-9a23-bff650e487f0' User entered 'No (N)'	System	13 Sep 2020 22:25:25
	System	13 Sep 2020 22:25:25

US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:34:16

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-13T18:25:19', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '931468c4-65cb-443a-9a23-bff650e487f0' User entered 'None (1)'	System	13 Sep 2020 22:25:25
	System	13 Sep 2020 22:25:25

US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:34:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-13T18:25:22', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '931468c4-65cb-443a-9a23-bff650e487f0' User entered '13 Sep 2020 18:25'	System	13 Sep 2020 22:25:25
	System	13 Sep 2020 22:25:25

US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:34:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 15:26:45

US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:34:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 15:26:45

US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
Data entry locked.	System	11 Sep 2020 15:26:45
User entered 'Day 4'	System	11 Sep 2020 15:26:45

US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:34:16

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-14T18:02:59', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'b4f11a0e-3700-496d-aeca-7ad036cb26c9' User entered 'None (1)'	System	14 Sep 2020 22:03:15
	System	14 Sep 2020 22:03:15

US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:34:16

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-14T18:03:03', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'b4f11a0e-3700-496d-aeca-7ad036cb26c9' User entered 'No (N)'	System	14 Sep 2020 22:03:15
	System	14 Sep 2020 22:03:15



US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:34:16

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-14T18:03:06', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'b4f11a0e-3700-496d-aeca-7ad036cb26c9' User entered 'No (N)'	System	14 Sep 2020 22:03:15
	System	14 Sep 2020 22:03:15

US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:34:16

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-14T18:03:09', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'b4f11a0e-3700-496d-aeca-7ad036cb26c9' User entered 'None (1)'	System	14 Sep 2020 22:03:15
	System	14 Sep 2020 22:03:15

US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:34:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-14T18:03:12', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'b4f11a0e-3700-496d-aeca-7ad036cb26c9' User entered '14 Sep 2020 18:03'	System	14 Sep 2020 22:03:15
	System	14 Sep 2020 22:03:15

US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:34:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 15:26:45

US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:34:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 15:26:45

US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
Data entry locked.	System	11 Sep 2020 15:26:45
User entered 'Day 5'	System	11 Sep 2020 15:26:45

US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:34:16

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-15T17:27:01', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'e1601745-71b7-4ac7-ae41-f120487feed' User entered 'None (1)'	System	15 Sep 2020 21:27:15
	System	15 Sep 2020 21:27:15

US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:34:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-15T17:27:05', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'e1601745-71b7-4ac7-ae41-f120487feed' User entered 'No (N)'	System	15 Sep 2020 21:27:15
	System	15 Sep 2020 21:27:15



US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:34:16

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-15T17:27:07', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'e1601745-71b7-4ac7-ae41-f120487feed' User entered 'No (N)'	System	15 Sep 2020 21:27:15
	System	15 Sep 2020 21:27:15

US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:34:16

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-15T17:27:10', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'e1601745-71b7-4ac7-ae41-f120487feed' User entered 'None (1)'	System	15 Sep 2020 21:27:15
	System	15 Sep 2020 21:27:15

US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:34:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-15T17:27:12', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'e1601745-71b7-4ac7-ae41-f120487feed' User entered '15 Sep 2020 17:27'	System	15 Sep 2020 21:27:15
	System	15 Sep 2020 21:27:15

US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:34:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 15:26:45

US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:34:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 15:26:45

US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
Data entry locked.	System	11 Sep 2020 15:26:45
User entered 'Day 6'	System	11 Sep 2020 15:26:45

US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:34:16

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-16T16:40:42', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '24fc8955-dd0e-494f-8d35-de6a3f47f64a' User entered 'None (1)'	System	16 Sep 2020 20:40:59
	System	16 Sep 2020 20:40:59

US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:34:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-16T16:40:46', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '24fc8955-dd0e-494f-8d35-de6a3f47f64a' User entered 'No (N)'	System	16 Sep 2020 20:40:59
	System	16 Sep 2020 20:40:59



US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:34:16

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-16T16:40:49', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '24fc8955-dd0e-494f-8d35-de6a3f47f64a' User entered 'No (N)'	System	16 Sep 2020 20:40:59
	System	16 Sep 2020 20:40:59

US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:34:16

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-16T16:40:53', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '24fc8955-dd0e-494f-8d35-de6a3f47f64a' User entered 'None (1)'	System	16 Sep 2020 20:40:59
	System	16 Sep 2020 20:40:59

US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:34:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-16T16:40:55', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '24fc8955-dd0e-494f-8d35-de6a3f47f64a' User entered '16 Sep 2020 16:40'	System	16 Sep 2020 20:40:59
	System	16 Sep 2020 20:40:59

US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:34:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 15:26:45

**US3412243**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:34:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 15:26:45

US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
Data entry locked.	System	11 Sep 2020 15:26:45
User entered 'Day 7'	System	11 Sep 2020 15:26:45

US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:34:16

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-17T17:32:15', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '9465b689-9af3-47b7-a8f3-118c78baf3f1' User entered 'None (1)'	System	17 Sep 2020 21:32:42
	System	17 Sep 2020 21:32:42

US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:34:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-17T17:32:19', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '9465b689-9af3-47b7-a8f3-118c78baf3f1' User entered 'No (N)'	System	17 Sep 2020 21:32:42
	System	17 Sep 2020 21:32:42



US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:34:16

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-17T17:32:24', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '9465b689-9af3-47b7-a8f3-118c78baf3f1' User entered 'No (N)'	System	17 Sep 2020 21:32:42
	System	17 Sep 2020 21:32:42

US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:34:16

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-17T17:32:26', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '9465b689-9af3-47b7-a8f3-118c78baf3f1' User entered 'None (1)'	System	17 Sep 2020 21:32:42
	System	17 Sep 2020 21:32:42

US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:34:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-17T17:32:29', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '9465b689-9af3-47b7-a8f3-118c78baf3f1' User entered '17 Sep 2020 17:32'	System	17 Sep 2020 21:32:42
	System	17 Sep 2020 21:32:42

**US3412243**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:34:16**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 15:26:45

US3412243

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:34:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 15:26:45

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
Data entry locked.	System	11 Sep 2020 15:26:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 15:26:45

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:16

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-11T12:08:57', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '81b4a908-ba4d-410f-b3dc-ebfe576a66e3' User entered 'None (0)'	System	11 Sep 2020 16:09:25
	System	11 Sep 2020 16:09:25

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:16

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-11T12:09:00', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '81b4a908-ba4d-410f-b3dc-ebfe576a66e3' User entered 'None (0)'	System	11 Sep 2020 16:09:25
	System	11 Sep 2020 16:09:25



US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:16

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-11T12:09:03', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '81b4a908-ba4d-410f-b3dc-ebfe576a66e3' User entered 'None (0)'	System	11 Sep 2020 16:09:25
	System	11 Sep 2020 16:09:25

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:16

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-11T12:09:05', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '81b4a908-ba4d-410f-b3dc-ebfe576a66e3' User entered 'None (0)'	System	11 Sep 2020 16:09:25
	System	11 Sep 2020 16:09:25

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:16

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-11T12:09:09', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '81b4a908-ba4d-410f-b3dc-ebfe576a66e3' User entered 'None (0)'	System	11 Sep 2020 16:09:25
	System	11 Sep 2020 16:09:25

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:16

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-11T12:09:11', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '81b4a908-ba4d-410f-b3dc-ebfe576a66e3' User entered 'None (0)'	System	11 Sep 2020 16:09:25
	System	11 Sep 2020 16:09:25

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:16

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-11T12:09:16', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '81b4a908-ba4d-410f-b3dc-ebfe576a66e3' User entered 'No (N)'	System	11 Sep 2020 16:09:25
	System	11 Sep 2020 16:09:25

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-11T12:09:19', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '81b4a908-ba4d-410f-b3dc-ebfe576a66e3' User entered '11 Sep 2020 12:09'	System	11 Sep 2020 16:09:25
	System	11 Sep 2020 16:09:25

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '11 Sep 2020 11:45'	System	11 Sep 2020 15:26:45

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:34:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '11 Sep 2020 14:15'	System	11 Sep 2020 15:26:45



US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
Data entry locked.	System	11 Sep 2020 15:26:45
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 15:26:45

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:16

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-11T18:50:33', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '783c0a3e-ed03-42a5-ab68-65adecf432f8' User entered 'None (0)'	System	11 Sep 2020 22:51:04
	System	11 Sep 2020 22:51:04

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:16

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-11T18:50:36', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '783c0a3e-ed03-42a5-ab68-65adecf432f8' User entered 'None (0)'	System	11 Sep 2020 22:51:04
	System	11 Sep 2020 22:51:04

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:16

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-11T18:50:40', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '783c0a3e-ed03-42a5-ab68-65adecf432f8' User entered 'None (0)'	System	11 Sep 2020 22:51:04
	System	11 Sep 2020 22:51:04

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:16

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-11T18:50:42', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '783c0a3e-ed03-42a5-ab68-65adecf432f8' User entered 'None (0)'	System	11 Sep 2020 22:51:04
	System	11 Sep 2020 22:51:04

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:16

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-11T18:50:45', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '783c0a3e-ed03-42a5-ab68-65adecf432f8' User entered 'None (0)'	System	11 Sep 2020 22:51:04
	System	11 Sep 2020 22:51:04

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:16

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-11T18:50:47', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '783c0a3e-ed03-42a5-ab68-65adecf432f8' User entered 'None (0)'	System	11 Sep 2020 22:51:04
	System	11 Sep 2020 22:51:04

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:16

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-11T18:50:52', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '783c0a3e-ed03-42a5-ab68-65adecf432f8'	System	11 Sep 2020 22:51:04
User entered 'No (N)'	System	11 Sep 2020 22:51:04



US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:34:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-11T18:50:55', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '783c0a3e-ed03-42a5-ab68-65adecf432f8'	System	11 Sep 2020 22:51:04
User entered '11 Sep 2020 18:50'	System	11 Sep 2020 22:51:04

**US3412243**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:34:16**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '11 Sep 2020 15:10'	System	11 Sep 2020 15:26:45

**US3412243**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:34:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 15:26:45

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
Data entry locked.	System	11 Sep 2020 15:26:45
User entered 'Day 2'	System	11 Sep 2020 15:26:45

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:16

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-12T18:20:28', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '5c4f03d8-51c8-45ab-8fa8-79bc0deac088' User entered 'None (0)'	System	12 Sep 2020 22:20:55
	System	12 Sep 2020 22:20:55

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:16

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-12T18:20:31', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '5c4f03d8-51c8-45ab-8fa8-79bc0deac088' User entered 'None (0)'	System	12 Sep 2020 22:20:55
	System	12 Sep 2020 22:20:55

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:16

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-12T18:20:33', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '5c4f03d8-51c8-45ab-8fa8-79bc0deac088' User entered 'None (0)'	System	12 Sep 2020 22:20:55
	System	12 Sep 2020 22:20:55

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:16

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-12T18:20:36', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '5c4f03d8-51c8-45ab-8fa8-79bc0deac088' User entered 'None (0)'	System	12 Sep 2020 22:20:55
	System	12 Sep 2020 22:20:55



US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:16

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-12T18:20:39', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '5c4f03d8-51c8-45ab-8fa8-79bc0deac088' User entered 'None (0)'	System	12 Sep 2020 22:20:55
	System	12 Sep 2020 22:20:55

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:16

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-12T18:20:42', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '5c4f03d8-51c8-45ab-8fa8-79bc0deac088' User entered 'None (0)'	System	12 Sep 2020 22:20:55
	System	12 Sep 2020 22:20:55

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:16

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-12T18:20:47', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '5c4f03d8-51c8-45ab-8fa8-79bc0deac088' User entered 'No (N)'	System	12 Sep 2020 22:20:55
	System	12 Sep 2020 22:20:55

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:34:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-12T18:20:52', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '5c4f03d8-51c8-45ab-8fa8-79bc0deac088'	System	12 Sep 2020 22:20:55
User entered '12 Sep 2020 18:20'	System	12 Sep 2020 22:20:55

**US3412243**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:34:16**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 15:26:45

**US3412243**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:34:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 15:26:45

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
Data entry locked.	System	11 Sep 2020 15:26:45
User entered 'Day 3'	System	11 Sep 2020 15:26:45

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:16

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-13T18:25:27', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '24f5f217-9763-4242-be0d-f4b47dc5eb5d' User entered 'None (0)'	System	13 Sep 2020 22:25:45
	System	13 Sep 2020 22:25:45



US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:16

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-13T18:25:29', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '24f5f217-9763-4242-be0d-f4b47dc5eb5d' User entered 'None (0)'	System	13 Sep 2020 22:25:45
	System	13 Sep 2020 22:25:45

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:16

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-13T18:25:32', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '24f5f217-9763-4242-be0d-f4b47dc5eb5d' User entered 'None (0)'	System	13 Sep 2020 22:25:45
	System	13 Sep 2020 22:25:45

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:16

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-13T18:25:34', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '24f5f217-9763-4242-be0d-f4b47dc5eb5d' User entered 'None (0)'	System	13 Sep 2020 22:25:45
	System	13 Sep 2020 22:25:45

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:16

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-13T18:25:36', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '24f5f217-9763-4242-be0d-f4b47dc5eb5d' User entered 'None (0)'	System	13 Sep 2020 22:25:45
	System	13 Sep 2020 22:25:45

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:16

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-13T18:25:38', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '24f5f217-9763-4242-be0d-f4b47dc5eb5d' User entered 'None (0)'	System	13 Sep 2020 22:25:45
	System	13 Sep 2020 22:25:45

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:16

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-13T18:25:41', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '24f5f217-9763-4242-be0d-f4b47dc5eb5d' User entered 'No (N)'	System	13 Sep 2020 22:25:45
	System	13 Sep 2020 22:25:45

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-13T18:25:44', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '24f5f217-9763-4242-be0d-f4b47dc5eb5d' User entered '13 Sep 2020 18:25'	System	13 Sep 2020 22:25:45
	System	13 Sep 2020 22:25:45

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:34:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 15:26:45



**US3412243**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:34:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 15:26:45

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
Data entry locked.	System	11 Sep 2020 15:26:45
User entered 'Day 4'	System	11 Sep 2020 15:26:45

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:16

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-14T18:03:18', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '70df7cee-55f8-427b-8145-3f7001649780' User entered 'None (0)'	System	14 Sep 2020 22:03:44
	System	14 Sep 2020 22:03:44

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:16

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-14T18:03:21', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '70df7cee-55f8-427b-8145-3f7001649780' User entered 'None (0)'	System	14 Sep 2020 22:03:44
	System	14 Sep 2020 22:03:44

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:16

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-14T18:03:24', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '70df7cee-55f8-427b-8145-3f7001649780' User entered 'None (0)'	System	14 Sep 2020 22:03:44
	System	14 Sep 2020 22:03:44

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:16

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-14T18:03:26', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '70df7cee-55f8-427b-8145-3f7001649780' User entered 'None (0)'	System	14 Sep 2020 22:03:44
	System	14 Sep 2020 22:03:44

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:16

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-14T18:03:28', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '70df7cee-55f8-427b-8145-3f7001649780' User entered 'None (0)'	System	14 Sep 2020 22:03:44
	System	14 Sep 2020 22:03:44

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:16

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-14T18:03:31', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '70df7cee-55f8-427b-8145-3f7001649780' User entered 'None (0)'	System	14 Sep 2020 22:03:44
	System	14 Sep 2020 22:03:44



US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:16

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-14T18:03:36', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '70df7cee-55f8-427b-8145-3f7001649780' User entered 'No (N)'	System	14 Sep 2020 22:03:44
	System	14 Sep 2020 22:03:44

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-14T18:03:40', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '70df7cee-55f8-427b-8145-3f7001649780' User entered '14 Sep 2020 18:03'	System	14 Sep 2020 22:03:44
	System	14 Sep 2020 22:03:44

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 15:26:45

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:34:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 15:26:45

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
Data entry locked.	System	11 Sep 2020 15:26:45
User entered 'Day 5'	System	11 Sep 2020 15:26:45

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:16

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-15T17:27:17', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'f96990a7-6561-4782-ac8d-7039345a3198' User entered 'None (0)'	System	15 Sep 2020 21:27:38
	System	15 Sep 2020 21:27:38

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:16

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-15T17:27:19', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'f96990a7-6561-4782-ac8d-7039345a3198' User entered 'None (0)'	System	15 Sep 2020 21:27:38
	System	15 Sep 2020 21:27:38

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:16

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-15T17:27:22', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'f96990a7-6561-4782-ac8d-7039345a3198' User entered 'None (0)'	System	15 Sep 2020 21:27:38
	System	15 Sep 2020 21:27:38



US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:16

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-15T17:27:25', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'f96990a7-6561-4782-ac8d-7039345a3198' User entered 'None (0)'	System	15 Sep 2020 21:27:38
	System	15 Sep 2020 21:27:38

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:16

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-15T17:27:28', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'f96990a7-6561-4782-ac8d-7039345a3198' User entered 'None (0)'	System	15 Sep 2020 21:27:38
	System	15 Sep 2020 21:27:38

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:16

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-15T17:27:30', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'f96990a7-6561-4782-ac8d-7039345a3198' User entered 'None (0)'	System	15 Sep 2020 21:27:38
	System	15 Sep 2020 21:27:38

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:16

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-15T17:27:34', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'f96990a7-6561-4782-ac8d-7039345a3198'	System	15 Sep 2020 21:27:38
User entered 'No (N)'	System	15 Sep 2020 21:27:38

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-15T17:27:36', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'f96990a7-6561-4782-ac8d-7039345a3198' User entered '15 Sep 2020 17:27'	System	15 Sep 2020 21:27:38
	System	15 Sep 2020 21:27:38

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 15:26:45

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:34:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 15:26:45

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
Data entry locked.	System	11 Sep 2020 15:26:45
User entered 'Day 6'	System	11 Sep 2020 15:26:45



US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:16

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-16T16:41:00', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '8db94d94-c28a-4097-b8cd-7396ef642379' User entered 'None (0)'	System	16 Sep 2020 20:41:25
	System	16 Sep 2020 20:41:25

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:16

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-16T16:41:02', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '8db94d94-c28a-4097-b8cd-7396ef642379' User entered 'None (0)'	System	16 Sep 2020 20:41:25
	System	16 Sep 2020 20:41:25

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:16

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-16T16:41:04', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '8db94d94-c28a-4097-b8cd-7396ef642379' User entered 'None (0)'	System	16 Sep 2020 20:41:25
	System	16 Sep 2020 20:41:25

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:16

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-16T16:41:06', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '8db94d94-c28a-4097-b8cd-7396ef642379' User entered 'None (0)'	System	16 Sep 2020 20:41:25
	System	16 Sep 2020 20:41:25

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:16

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-16T16:41:09', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '8db94d94-c28a-4097-b8cd-7396ef642379' User entered 'None (0)'	System	16 Sep 2020 20:41:25
	System	16 Sep 2020 20:41:25

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:16

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-16T16:41:11', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '8db94d94-c28a-4097-b8cd-7396ef642379' User entered 'None (0)'	System	16 Sep 2020 20:41:25
	System	16 Sep 2020 20:41:25

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:16

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-16T16:41:16', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '8db94d94-c28a-4097-b8cd-7396ef642379' User entered 'No (N)'	System	16 Sep 2020 20:41:25
	System	16 Sep 2020 20:41:25

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-16T16:41:19', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '8db94d94-c28a-4097-b8cd-7396ef642379' User entered '16 Sep 2020 16:41'	System	16 Sep 2020 20:41:25
	System	16 Sep 2020 20:41:25



US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 15:26:45

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:34:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 15:26:45

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
Data entry locked.	System	11 Sep 2020 15:26:45
User entered 'Day 7'	System	11 Sep 2020 15:26:45

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:16

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-17T17:32:34', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'ff885ff5-3d97-44cc-a9ba-c92a1efabae3' User entered 'None (0)'	System	17 Sep 2020 21:32:56
	System	17 Sep 2020 21:32:56

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:16

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-17T17:32:36', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'ff885ff5-3d97-44cc-a9ba-c92a1efabae3'	System	17 Sep 2020 21:32:56
User entered 'None (0)'	System	17 Sep 2020 21:32:56

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:16

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-17T17:32:38', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'ff885ff5-3d97-44cc-a9ba-c92a1efabae3' User entered 'None (0)'	System	17 Sep 2020 21:32:56
	System	17 Sep 2020 21:32:56

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:16

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-17T17:32:40', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'ff885ff5-3d97-44cc-a9ba-c92a1efabae3'	System	17 Sep 2020 21:32:56
User entered 'None (0)'	System	17 Sep 2020 21:32:56

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:16

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-17T17:32:42', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'ff885ff5-3d97-44cc-a9ba-c92a1efabae3'	System	17 Sep 2020 21:32:56
User entered 'None (0)'	System	17 Sep 2020 21:32:56



US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:16

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-17T17:32:44', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'ff885ff5-3d97-44cc-a9ba-c92a1efabae3'	System	17 Sep 2020 21:32:56
User entered 'None (0)'	System	17 Sep 2020 21:32:56

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:16

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-17T17:32:48', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'ff885ff5-3d97-44cc-a9ba-c92a1efabae3'	System	17 Sep 2020 21:32:56
User entered 'No (N)'	System	17 Sep 2020 21:32:56

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-09-17T17:32:50', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'ff885ff5-3d97-44cc-a9ba-c92a1efabae3'	System	17 Sep 2020 21:32:56
User entered '17 Sep 2020 17:32'	System	17 Sep 2020 21:32:56

US3412243

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:34:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 15:26:45

**US3412243**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:34:16**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 15:26:45

**US3412243**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:34:16**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 14:54:39

**US3412243**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:34:16**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '18 Sep 2020'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 14:54:39

**US3412243**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:34:16**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 14:54:39



**US3412243**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:34:16**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 14:54:39

**US3412243**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:34:16**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 14:54:44

**US3412243**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:34:16**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User entered 'I'	System	18 Sep 2020 14:54:44

**US3412243**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:34:16**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'Yes (Y)'	Mason Urban (b) (4)	25 Sep 2020 18:18:22

**US3412243**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:34:16**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '25 Sep 2020'	Mason Urban (b) (4)	25 Sep 2020 18:18:22

**US3412243**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:34:16**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	25 Sep 2020 18:18:22

**US3412243**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:34:16**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered empty.	Mason Urban (b) (4)	25 Sep 2020 18:18:22

US3412243

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'Yes (Y)'	Mason Urban (b) (4)	25 Sep 2020 18:18:15



**US3412243**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:34:16**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User entered 'I'	System	25 Sep 2020 18:18:15

**US3412243**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:34:16**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'Yes (Y)'	Mason Urban (b) (4)	02 Oct 2020 15:48:04

**US3412243**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:34:16**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '2 Oct 2020'	Mason Urban (b) (4)	02 Oct 2020 15:48:04

**US3412243**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:34:16**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	02 Oct 2020 15:48:04

**US3412243**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:34:16**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered empty.	Mason Urban (b) (4)	02 Oct 2020 15:48:04

US3412243

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'Yes (Y)'	Mason Urban (b) (4)	02 Oct 2020 15:48:08

**US3412243**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:34:16**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User entered 'I'	System	02 Oct 2020 15:48:08

US3412243

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	09 Oct 2020 16:49:35



**US3412243**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:34:16**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '9 Oct 2020'	Melissa Fuson (b) (4)	09 Oct 2020 16:49:35

US3412243

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:16

[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 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'Clinic (Clinic)'	Melissa Fuson (b) (4)	09 Oct 2020 16:49:35

**US3412243**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:34:16**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User entered 'VISIT3'	System	09 Oct 2020 16:49:35

US3412243

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'No (N)'	Melissa Fuson (b) (4)	09 Oct 2020 16:49:45

US3412243

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered empty.	Melissa Fuson (b) (4)	09 Oct 2020 16:49:45

**US3412243**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:34:16**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered empty.	Melissa Fuson (b) (4)	09 Oct 2020 16:49:45

**US3412243**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:34:16**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User entered empty.	System	09 Oct 2020 16:49:45

US3412243

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered empty.	Melissa Fuson (b) (4)	09 Oct 2020 16:49:45



US3412243

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered empty.	Melissa Fuson (b) (4)	09 Oct 2020 16:49:45

**US3412243**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:34:16**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered empty.	Melissa Fuson (b) (4)	09 Oct 2020 16:49:45

**US3412243**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:34:16**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered empty.	Melissa Fuson (b) (4)	09 Oct 2020 16:49:45

**US3412243**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:34:16**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User entered empty.	System	09 Oct 2020 16:49:45

US3412243

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered empty.	Melissa Fuson (b) (4)	09 Oct 2020 16:49:45

US3412243

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User entered empty.	System	09 Oct 2020 16:49:45

US3412243

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered empty.	Melissa Fuson (b) (4)	09 Oct 2020 16:49:45

**US3412243**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:34:16**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User entered empty.	System	09 Oct 2020 16:49:45



US3412243

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered empty.	Melissa Fuson (b) (4)	09 Oct 2020 16:49:45

**US3412243**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:34:16**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User entered empty.	System	09 Oct 2020 16:49:45

**US3412243**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:34:16**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13

**US3412243**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:34:16**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13

US3412243

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 15:09:58
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	09 Oct 2020 16:49:59

US3412243

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered empty; reason for change Data Entry Error	Melissa Fuson (b) (4)	28 Jan 2021 15:09:58
User entered '9 Oct 2020'	Melissa Fuson (b) (4)	09 Oct 2020 16:49:59

US3412243

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	09 Oct 2020 16:50:24

US3412243

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:16

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '9 Oct 2020'	Melissa Fuson (b) (4)	09 Oct 2020 16:50:24



**US3412243**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:34:16**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered '09:45'	Melissa Fuson (b) (4)	09 Oct 2020 16:50:24

**US3412243**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:34:16**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User entered '9 Oct 2020 09:45'	System	09 Oct 2020 16:50:24

US3412243

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:02:11
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	09 Oct 2020 16:50:36

**US3412243**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:34:16**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User entered 'I'	System	09 Oct 2020 16:50:36

US3412243

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
Data entry locked.	System	14 Aug 2020 16:10:01
User entered 'Day 64'	System	14 Aug 2020 16:10:01

**US3412243**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-10-14T12:51:54', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '2f19f01e-da6d-42d7-af90-f219af734bc9'	System	14 Oct 2020 16:52:17
User entered 'No (N)'	System	14 Oct 2020 16:52:17

US3412243

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-10-14T12:52:00', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '2f19f01e-da6d-42d7-af90-f219af734bc9'	System	14 Oct 2020 16:52:17
User entered 'No (N)'	System	14 Oct 2020 16:52:17

**US3412243**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-10-14T12:52:14', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '2f19f01e-da6d-42d7-af90-f219af734bc9' User entered '14 Oct 2020 12:52:14'	System	14 Oct 2020 16:52:17
	System	14 Oct 2020 16:52:17



**US3412243**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
Data entry locked.	System	14 Aug 2020 16:10:01
User entered '14 Oct 2020 00:01'	System	14 Aug 2020 16:10:01

**US3412243**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
Data entry locked.	System	14 Aug 2020 16:10:01
User entered '18 Oct 2020 23:59'	System	14 Aug 2020 16:10:01

**US3412243**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
Data entry locked.	System	14 Aug 2020 16:10:01
User entered 'Day 71'	System	14 Aug 2020 16:10:01

US3412243

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-10-22T18:06:02', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '79ac4f65-6612-418a-a2c9-9cf8f7fbe1df' User entered 'No (N)'	System	22 Oct 2020 22:06:27
	System	22 Oct 2020 22:06:27

US3412243

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-10-22T18:06:08', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '79ac4f65-6612-418a-a2c9-9cf8f7fbe1df' User entered 'No (N)'	System	22 Oct 2020 22:06:27
	System	22 Oct 2020 22:06:27

**US3412243**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-10-22T18:06:25', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '79ac4f65-6612-418a-a2c9-9cf8f7fbe1df' User entered '22 Oct 2020 18:06:25'	System	22 Oct 2020 22:06:27
	System	22 Oct 2020 22:06:27

**US3412243**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
Data entry locked.	System	14 Aug 2020 16:10:01
User entered '21 Oct 2020 00:01'	System	14 Aug 2020 16:10:01

**US3412243**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
Data entry locked.	System	14 Aug 2020 16:10:01
User entered '25 Oct 2020 23:59'	System	14 Aug 2020 16:10:01



US3412243

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
Data entry locked.	System	14 Aug 2020 16:10:01
User entered 'Day 78'	System	14 Aug 2020 16:10:01

**US3412243**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-10-28T10:56:49', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '3e6c4221-bfcb-4d4f-8e5b-5f4fcdbd6e27d' User entered 'No (N)'	System	28 Oct 2020 14:57:13
	System	28 Oct 2020 14:57:13

US3412243

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-10-28T10:56:56', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '3e6c4221-bfcb-4d4f-8e5b-5f4fcdbd6e27d' User entered 'No (N)'	System	28 Oct 2020 14:57:13
	System	28 Oct 2020 14:57:13

**US3412243**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-10-28T10:57:08', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '3e6c4221-bfcb-4d4f-8e5b-5f4fcdbd6e27d' User entered '28 Oct 2020 10:57:08'	System	28 Oct 2020 14:57:13
	System	28 Oct 2020 14:57:13

**US3412243**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
Data entry locked.	System	14 Aug 2020 16:10:01
User entered '28 Oct 2020 00:01'	System	14 Aug 2020 16:10:01

**US3412243**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
Data entry locked.	System	14 Aug 2020 16:10:01
User entered '01 Nov 2020 23:59'	System	14 Aug 2020 16:10:01

US3412243

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
Data entry locked.	System	14 Aug 2020 16:10:01
User entered 'Day 92'	System	14 Aug 2020 16:10:01

US3412243

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-11-11T07:47:44', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '9e06d872-7af2-4ba8-81ba-90c50cc8dd0c' User entered 'No (N)'	System	11 Nov 2020 12:48:19
	System	11 Nov 2020 12:48:19



US3412243

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-11-11T07:48:11', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '9e06d872-7af2-4ba8-81ba-90c50cc8dd0c' User entered 'No (N)'	System	11 Nov 2020 12:48:19
	System	11 Nov 2020 12:48:19

**US3412243**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-11-11T07:48:16', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '9e06d872-7af2-4ba8-81ba-90c50cc8dd0c' User entered '11 Nov 2020 07:48:16'	System	11 Nov 2020 12:48:19
	System	11 Nov 2020 12:48:19

**US3412243**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
Data entry locked.	System	14 Aug 2020 16:10:01
User entered '11 Nov 2020 00:01'	System	14 Aug 2020 16:10:01

**US3412243**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
Data entry locked.	System	14 Aug 2020 16:10:01
User entered '15 Nov 2020 23:59'	System	14 Aug 2020 16:10:01

**US3412243**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
Data entry locked.	System	14 Aug 2020 16:10:01
User entered 'Day 99'	System	14 Aug 2020 16:10:01

US3412243

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-11-18T06:53:48', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'e928d0f3-1c4e-4c20-9afc-fad241f7a869' User entered 'No (N)'	System	18 Nov 2020 11:54:17
	System	18 Nov 2020 11:54:17

US3412243

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:34:16

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-11-18T06:53:53', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'e928d0f3-1c4e-4c20-9afc-fad241f7a869'	System	18 Nov 2020 11:54:17
User entered 'No (N)'	System	18 Nov 2020 11:54:17

**US3412243**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-11-18T06:54:13', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'e928d0f3-1c4e-4c20-9afc-fad241f7a869' User entered '18 Nov 2020 06:54:13'	System	18 Nov 2020 11:54:17
	System	18 Nov 2020 11:54:17



**US3412243**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
Data entry locked.	System	14 Aug 2020 16:10:01
User entered '18 Nov 2020 00:01'	System	14 Aug 2020 16:10:01

**US3412243**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:55:23
Data entry locked.	System	14 Aug 2020 16:10:01
User entered '22 Nov 2020 23:59'	System	14 Aug 2020 16:10:01

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[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 (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-11-19T12:14:41', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '11415288-8714-4667-93c3-113d0257547e' User entered 'No (N)'	System	19 Nov 2020 17:14:56

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

Have you been exposed to someone with 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 (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-11-19T12:14:46', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '11415288-8714-4667-93c3-113d0257547e' User entered 'No (N)'	System	19 Nov 2020 17:14:56
	System	19 Nov 2020 17:14:56

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-11-19T12:14:53', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '11415288-8714-4667-93c3-113d0257547e' User entered '19 Nov 2020 12:14:53'	System	19 Nov 2020 17:14:56
	System	19 Nov 2020 17:14:56

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '15 Nov 2020 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '19 Nov 2020 23:59'	System	19 Nov 2020 07:21:33



**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[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 (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-11-22T14:24:57', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'c59b20d8-6a95-4e8f-b41f-b47d3f03d13b' User entered 'No (N)'	System	22 Nov 2020 19:25:08

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

Have you been exposed to someone with 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 (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-11-22T14:25:00', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'c59b20d8-6a95-4e8f-b41f-b47d3f03d13b' User entered 'No (N)'	System	22 Nov 2020 19:25:08

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-11-22T14:25:04', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'c59b20d8-6a95-4e8f-b41f-b47d3f03d13b' User entered '22 Nov 2020 14:25:04'	System	22 Nov 2020 19:25:08
	System	22 Nov 2020 19:25:08

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[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 (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-11-29T16:17:14', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '2235f2bf-22f1-42f4-a47b-862ef6cbe7a9' User entered 'No (N)'	System	29 Nov 2020 21:17:41
	System	29 Nov 2020 21:17:41



**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

Have you been exposed to someone with 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 (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-11-29T16:17:20', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '2235f2bf-22f1-42f4-a47b-862ef6cbe7a9' User entered 'No (N)'	System	29 Nov 2020 21:17:41
	System	29 Nov 2020 21:17:41

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-11-29T16:17:38', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '2235f2bf-22f1-42f4-a47b-862ef6cbe7a9' User entered '29 Nov 2020 16:17:38'	System	29 Nov 2020 21:17:41
	System	29 Nov 2020 21:17:41

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[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 (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-12-06T16:54:52', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '20182afc-b4ad-4766-8125-f4344ffd556c' User entered 'No (N)'	System	06 Dec 2020 21:55:04
	System	06 Dec 2020 21:55:04

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

Have you been exposed to someone with 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 (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-12-06T16:54:55', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '20182afc-b4ad-4766-8125-f4344ffd5556'	System	06 Dec 2020 21:55:04
User entered 'No (N)'	System	06 Dec 2020 21:55:04

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-12-06T16:55:00', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '20182afc-b4ad-4766-8125-f4344ffd5556'	System	06 Dec 2020 21:55:04
User entered '06 Dec 2020 16:55:00'	System	06 Dec 2020 21:55:04



**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[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 (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-12-13T13:14:13', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '5d41aac3-17e8-4a09-a505-9bee470a011d' User entered 'No (N)'	System	13 Dec 2020 18:14:25
	System	13 Dec 2020 18:14:25

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

Have you been exposed to someone with 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 (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-12-13T13:14:18', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '5d41aac3-17e8-4a09-a505-9bee470a011d' User entered 'No (N)'	System	13 Dec 2020 18:14:25
	System	13 Dec 2020 18:14:25

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-12-13T13:14:23', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '5d41aac3-17e8-4a09-a505-9bee470a011d' User entered '13 Dec 2020 13:14:23'	System	13 Dec 2020 18:14:25
	System	13 Dec 2020 18:14:25

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 07:21:33



**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[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 (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-12-20T15:15:37', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'ceec462-8fa4-47a9-9c63-49bbd3c0f85b' User entered 'No (N)'	System	20 Dec 2020 20:15:51
	System	20 Dec 2020 20:15:51

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

Have you been exposed to someone with 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 (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-12-20T15:15:42', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'ceec462-8fa4-47a9-9c63-49bbd3c0f85b' User entered 'No (N)'	System	20 Dec 2020 20:15:51
	System	20 Dec 2020 20:15:51

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-12-20T15:15:48', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'ceec462-8fa4-47a9-9c63-49bbd3c0f85b' User entered '20 Dec 2020 15:15:48'	System	20 Dec 2020 20:15:51
	System	20 Dec 2020 20:15:51

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[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 (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-12-27T13:20:50', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'd4e9b16c-4d01-4e8c-9e21-aed426eff57b' User entered 'No (N)'	System	27 Dec 2020 18:21:04
	System	27 Dec 2020 18:21:04



**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

Have you been exposed to someone with 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 (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-12-27T13:20:52', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'd4e9b16c-4d01-4e8c-9e21-aed426eff57b' User entered 'No (N)'	System	27 Dec 2020 18:21:04

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2020-12-27T13:21:01', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'd4e9b16c-4d01-4e8c-9e21-aed426eff57b' User entered '27 Dec 2020 13:21:01'	System	27 Dec 2020 18:21:04
	System	27 Dec 2020 18:21:04

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[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 (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2021-01-03T15:36:36', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '7a8d51e2-e3f2-4c35-bf17-c54d494cfe8c'	System	03 Jan 2021 20:36:46
User entered 'No (N)'	System	03 Jan 2021 20:36:46

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Have you been exposed to someone with 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 (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2021-01-03T15:36:39', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '7a8d51e2-e3f2-4c35-bf17-c54d494cfe8c' User entered 'No (N)'	System	03 Jan 2021 20:36:46

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2021-01-03T15:36:44', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '7a8d51e2-e3f2-4c35-bf17-c54d494cfe8c' User entered '03 Jan 2021 15:36:44'	System	03 Jan 2021 20:36:46
	System	03 Jan 2021 20:36:46



**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[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 (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2021-01-10T12:02:56', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '97809c87-1353-490f-bdf0-ed2cc77cbc1d'	System	10 Jan 2021 17:03:22
User entered 'No (N)'	System	10 Jan 2021 17:03:22

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Have you been exposed to someone with 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 (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2021-01-10T12:03:00', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '97809c87-1353-490f-bdf0-ed2cc77cbc1d' User entered 'No (N)'	System	10 Jan 2021 17:03:22
	System	10 Jan 2021 17:03:22

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2021-01-10T12:03:05', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '97809c87-1353-490f-bdf0-ed2cc77cbc1d' User entered '10 Jan 2021 12:03:05'	System	10 Jan 2021 17:03:22
	System	10 Jan 2021 17:03:22

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 07:21:33



**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[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 (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2021-01-20T12:43:30', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'e88c2cb9-0b5d-4ca4-a529-2db8dc9e449d' User entered 'No (N)'	System	20 Jan 2021 17:43:42
	System	20 Jan 2021 17:43:42

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

Have you been exposed to someone with 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 (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2021-01-20T12:43:32', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'e88c2cb9-0b5d-4ca4-a529-2db8dc9e449d' User entered 'No (N)'	System	20 Jan 2021 17:43:42

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2021-01-20T12:43:37', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'e88c2cb9-0b5d-4ca4-a529-2db8dc9e449d' User entered '20 Jan 2021 12:43:37'	System	20 Jan 2021 17:43:42

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[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 (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2021-01-24T14:26:58', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'd1c39bc7-a4b0-43d6-a626-5ccb856b9007'	System	24 Jan 2021 19:27:16
User entered 'No (N)'	System	24 Jan 2021 19:27:16



**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

Have you been exposed to someone with 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 (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2021-01-24T14:27:04', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'd1c39bc7-a4b0-43d6-a626-5ccb856b9007'	System	24 Jan 2021 19:27:16
User entered 'No (N)'	System	24 Jan 2021 19:27:16

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2021-01-24T14:27:12', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'd1c39bc7-a4b0-43d6-a626-5ccb856b9007' User entered '24 Jan 2021 14:27:12'	System	24 Jan 2021 19:27:16
	System	24 Jan 2021 19:27:16

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[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 (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2021-02-01T06:54:44', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '47a1924c-43e2-48fc-ac8d-6fb5e8781b06'	System	01 Feb 2021 11:54:59
User entered 'No (N)'	System	01 Feb 2021 11:54:59

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

Have you been exposed to someone with 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 (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2021-02-01T06:54:50', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '47a1924c-43e2-48fc-ac8d-6fb5e8781b06'	System	01 Feb 2021 11:54:59
User entered 'No (N)'	System	01 Feb 2021 11:54:59

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2021-02-01T06:54:56', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '47a1924c-43e2-48fc-ac8d-6fb5e8781b06' User entered '01 Feb 2021 06:54:56'	System	01 Feb 2021 11:54:59
	System	01 Feb 2021 11:54:59



**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[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 (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2021-02-08T13:51:10', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '1432852c-063c-4c60-af1c-a3e4310eb699' User entered 'No (N)'	System	08 Feb 2021 18:51:22
	System	08 Feb 2021 18:51:22

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

Have you been exposed to someone with 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 (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2021-02-08T13:51:15', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '1432852c-063c-4c60-af1c-a3e4310eb699' User entered 'No (N)'	System	08 Feb 2021 18:51:22

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2021-02-08T13:51:20', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '1432852c-063c-4c60-af1c-a3e4310eb699' User entered '08 Feb 2021 13:51:20'	System	08 Feb 2021 18:51:22
	System	08 Feb 2021 18:51:22

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 07:21:33



**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[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 (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2021-02-15T16:46:49', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'a215480a-29c7-4b49-8454-64ccfaa4cf6a' User entered 'No (N)'	System	15 Feb 2021 21:47:06
	System	15 Feb 2021 21:47:06

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

Have you been exposed to someone with 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 (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2021-02-15T16:46:54', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'a215480a-29c7-4b49-8454-64ccfaa4cf6a' User entered 'No (N)'	System	15 Feb 2021 21:47:06
	System	15 Feb 2021 21:47:06

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2021-02-15T16:47:01', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'a215480a-29c7-4b49-8454-64ccfaa4cf6a' User entered '15 Feb 2021 16:47:01'	System	15 Feb 2021 21:47:06
	System	15 Feb 2021 21:47:06

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[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 (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2021-02-21T10:49:05', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '343234d3-3ea7-4d3a-94cf-a95684383291' User entered 'No (N)'	System	21 Feb 2021 15:49:15
	System	21 Feb 2021 15:49:15



**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

Have you been exposed to someone with 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 (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2021-02-21T10:49:07', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '343234d3-3ea7-4d3a-94cf-a95684383291' User entered 'No (N)'	System	21 Feb 2021 15:49:15
	System	21 Feb 2021 15:49:15

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2021-02-21T10:49:11', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '343234d3-3ea7-4d3a-94cf-a95684383291' User entered '21 Feb 2021 10:49:11'	System	21 Feb 2021 15:49:15
	System	21 Feb 2021 15:49:15

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[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 (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2021-02-28T06:52:11-05:00', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '299db7e0-d428-4733-9766-1e2d3dbbd7db'	System	28 Feb 2021 11:52:24
User entered 'No (N)'	System	28 Feb 2021 11:52:24

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

Have you been exposed to someone with 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 (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2021-02-28T06:52:16-05:00', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '299db7e0-d428-4733-9766-1e2d3dbbd7db'	System	28 Feb 2021 11:52:24
User entered 'No (N)'	System	28 Feb 2021 11:52:24

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2021-02-28T06:52:21-05:00', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '299db7e0-d428-4733-9766-1e2d3dbbd7db'	System	28 Feb 2021 11:52:24
User entered '28 Feb 2021 11:52:21'	System	28 Feb 2021 11:52:24



**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[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 (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2021-03-08T10:47:20-05:00', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '84bb73be-b0d1-46a7-bd68-2eb323a21eef'	System	08 Mar 2021 15:47:41
User entered 'No (N)'	System	08 Mar 2021 15:47:41

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Have you been exposed to someone with 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 (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2021-03-08T10:47:25-05:00', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '84bb73be-b0d1-46a7-bd68-2eb323a21eef'	System	08 Mar 2021 15:47:41
User entered 'No (N)'	System	08 Mar 2021 15:47:41

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2021-03-08T10:47:35-05:00', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '84bb73be-b0d1-46a7-bd68-2eb323a21eef' User entered '08 Mar 2021 10:47:35'	System	08 Mar 2021 15:47:41
	System	08 Mar 2021 15:47:41

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 07:21:33



**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[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 (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2021-03-15T15:30:23-04:00', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '683c3a84-f508-4cd9-ad06-14b372c68e16'	System	15 Mar 2021 19:30:47
User entered 'No (N)'	System	15 Mar 2021 19:30:47

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

Have you been exposed to someone with 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 (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2021-03-15T15:30:26-04:00', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '683c3a84-f508-4cd9-ad06-14b372c68e16'	System	15 Mar 2021 19:30:47
User entered 'No (N)'	System	15 Mar 2021 19:30:47

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2021-03-15T15:30:44-04:00', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '683c3a84-f508-4cd9-ad06-14b372c68e16' User entered '15 Mar 2021 15:30:44'	System	15 Mar 2021 19:30:47
	System	15 Mar 2021 19:30:47

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[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 (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2021-03-23T13:31:43-04:00', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '27d3b941-71dd-4cd7-a3dd-5c05bbbb6fb0'	System	23 Mar 2021 17:31:56
User entered 'No (N)'	System	23 Mar 2021 17:31:56



**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

Have you been exposed to someone with 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 (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2021-03-23T13:31:46-04:00', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '27d3b941-71dd-4cd7-a3dd-5c05bbbb6fb0'	System	23 Mar 2021 17:31:56
User entered 'No (N)'	System	23 Mar 2021 17:31:56

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2021-03-23T13:31:54-04:00', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '27d3b941-71dd-4cd7-a3dd-5c05bbbb6fb0'	System	23 Mar 2021 17:31:56
User entered '23 Mar 2021 13:31:54'	System	23 Mar 2021 17:31:56

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[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 (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2021-03-28T01:17:58-04:00', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'b207753d-3fde-4919-8b25-515298be601a'	System	28 Mar 2021 05:18:19
User entered 'No (N)'	System	28 Mar 2021 05:18:19

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

Have you been exposed to someone with 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 (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2021-03-28T01:18:00-04:00', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'b207753d-3fde-4919-8b25-515298be601a'	System	28 Mar 2021 05:18:19
User entered 'No (N)'	System	28 Mar 2021 05:18:19

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2021-03-28T01:18:15-04:00', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: 'b207753d-3fde-4919-8b25-515298be601a'	System	28 Mar 2021 05:18:19
User entered '28 Mar 2021 01:18:15'	System	28 Mar 2021 05:18:19



**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[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 (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2021-04-05T09:12:30-04:00', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '5fc0e390-2b4a-4543-b172-e990dace5485'	System	05 Apr 2021 13:12:44
User entered 'No (N)'	System	05 Apr 2021 13:12:44

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

Have you been exposed to someone with 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 (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2021-04-05T09:12:33-04:00', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '5fc0e390-2b4a-4543-b172-e990dace5485'	System	05 Apr 2021 13:12:44
User entered 'No (N)'	System	05 Apr 2021 13:12:44

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2021-04-05T09:12:38-04:00', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '5fc0e390-2b4a-4543-b172-e990dace5485'	System	05 Apr 2021 13:12:44
User entered '05 Apr 2021 09:12:38'	System	05 Apr 2021 13:12:44

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 07:21:33



**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[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 (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2021-04-12T11:37:46-04:00', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '2ec17add-b76c-4861-8ccd-0173300816d2'	System	12 Apr 2021 15:37:59
User entered 'No (N)'	System	12 Apr 2021 15:37:59

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

Have you been exposed to someone with 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 (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2021-04-12T11:37:49-04:00', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '2ec17add-b76c-4861-8ccd-0173300816d2'	System	12 Apr 2021 15:37:59
User entered 'No (N)'	System	12 Apr 2021 15:37:59

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2021-04-12T11:37:54-04:00', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '2ec17add-b76c-4861-8ccd-0173300816d2'	System	12 Apr 2021 15:37:59
User entered '12 Apr 2021 11:37:54'	System	12 Apr 2021 15:37:59

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[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 (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2021-04-18T10:28:43-04:00', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '1adba09c-c210-4c45-b418-ef9e2829bd73'	System	18 Apr 2021 14:28:56
User entered 'No (N)'	System	18 Apr 2021 14:28:56



**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

Have you been exposed to someone with 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 (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2021-04-18T10:28:45-04:00', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '1adba09c-c210-4c45-b418-ef9e2829bd73'	System	18 Apr 2021 14:28:56
User entered 'No (N)'	System	18 Apr 2021 14:28:56

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2021-04-18T10:28:54-04:00', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '1adba09c-c210-4c45-b418-ef9e2829bd73'	System	18 Apr 2021 14:28:56
User entered '18 Apr 2021 10:28:54'	System	18 Apr 2021 14:28:56

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[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 (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2021-04-25T12:30:30-04:00', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '47035065-86f3-4e53-92ec-9eeabba1a422'	System	25 Apr 2021 16:30:41
User entered 'No (N)'	System	25 Apr 2021 16:30:41

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

Have you been exposed to someone with 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 (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2021-04-25T12:30:32-04:00', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '47035065-86f3-4e53-92ec-9eeabba1a422'	System	25 Apr 2021 16:30:41
User entered 'No (N)'	System	25 Apr 2021 16:30:41

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2021-04-25T12:30:38-04:00', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '47035065-86f3-4e53-92ec-9eeabba1a422'	System	25 Apr 2021 16:30:41
User entered '25 Apr 2021 12:30:38'	System	25 Apr 2021 16:30:41



**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[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 (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2021-05-02T11:12:25-04:00', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '5d8a8a15-49e6-42c8-a3e1-d44bf58793e8' User entered 'No (N)'	System	02 May 2021 15:12:46
	System	02 May 2021 15:12:46

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

Have you been exposed to someone with 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 (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2021-05-02T11:12:31-04:00', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '5d8a8a15-49e6-42c8-a3e1-d44bf58793e8' User entered 'No (N)'	System	02 May 2021 15:12:46

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2021-05-02T11:12:42-04:00', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '5d8a8a15-49e6-42c8-a3e1-d44bf58793e8'	System	02 May 2021 15:12:46
User entered '02 May 2021 11:12:42'	System	02 May 2021 15:12:46

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 07:21:33



**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 07:21:33



**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 07:21:33



**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 07:21:33



**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 07:21:33



**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 07:21:33



**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 07:21:33



**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 07:21:33



**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 07:21:33



**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 07:21:33



**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 07:21:33



**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 07:21:33



**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 07:21:33



**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 07:21:33



**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 07:21:33



**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 07:21:33



**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 07:21:33



**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 07:21:33



**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 07:21:33



**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 07:21:33



**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 07:21:33



**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 07:21:33



**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 07:21:33



**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 07:21:33



**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 07:21:33



**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 07:21:33



**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 07:21:33



**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 07:21:33



**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 07:21:33



**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '16 Oct 2022 00:01'	System	19 Nov 2020 07:21:33

**US3412243**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:34:16**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:21:33
Amendment Manager: User entered '20 Oct 2022 23:59'	System	19 Nov 2020 07:21:33

US3412243

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:34:16

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)	26 Apr 2021 00:44:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2021-02-28T06:54:38-05:00', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '1073ad5c-73de-4dca-a792-8d1a185d38ed' User entered 'No (N)'	System	28 Feb 2021 11:54:53
	System	28 Feb 2021 11:54:53

**US3412243**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 17:34:16**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:44:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (552133F6-0123-4892-B73A-03691CE7BBE9)', Time: '2021-02-28T06:54:51-05:00', User OID: 'PatientReportedOutcome (US3412243)', ODM File OID: '1073ad5c-73de-4dca-a792-8d1a185d38ed' User entered '28 Feb 2021 11:54:51'	System	28 Feb 2021 11:54:53
	System	28 Feb 2021 11:54:53

**US3412243**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:34:16**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:38:05
User entered 'Yes (Y)'	Mason Urban (b) (4)	06 Nov 2020 15:07:38

**US3412243**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:34:16**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:38:05
User entered '6 Nov 2020'	Mason Urban (b) (4)	06 Nov 2020 15:07:38



US3412243

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:38:05
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	06 Nov 2020 15:07:38

**US3412243**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:34:16**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:38:05
User entered empty.	Mason Urban (b) (4)	06 Nov 2020 15:07:38

US3412243

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:38:05
User entered 'Yes (Y)'	Mason Urban (b) (4)	06 Nov 2020 15:07:49

**US3412243**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:34:16**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:15:13
User entered 'I'	System	06 Nov 2020 15:07:49

**US3412243**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:34:16**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:35:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered 'Yes (Y)'	Mason Urban (b) (4)	08 Jan 2021 15:43:08

**US3412243**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:34:16**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:35:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered '9 Dec 2020'	Mason Urban (b) (4)	08 Jan 2021 15:43:08

**US3412243**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:34:16**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:35:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	08 Jan 2021 15:43:08

**US3412243**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:34:16**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:35:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered empty.	Mason Urban (b) (4)	08 Jan 2021 15:43:08



**US3412243**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:34:16**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:35:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered 'Yes (Y)'	Mason Urban (b) (4)	08 Jan 2021 15:42:54

**US3412243**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:34:16**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:35:05
User entered 'I'	System	08 Jan 2021 15:42:54

**US3412243**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:34:16**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:35:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered 'Yes (Y)'	Mason Urban (b) (4)	08 Jan 2021 15:44:35

**US3412243**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:34:16**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:35:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered '8 Jan 2021'	Mason Urban (b) (4)	08 Jan 2021 15:44:35

**US3412243**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:34:16**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:35:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	08 Jan 2021 15:44:35

**US3412243**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:34:16**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:35:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered empty.	Mason Urban (b) (4)	08 Jan 2021 15:44:35

US3412243

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:35:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered 'Yes (Y)'	Mason Urban (b) (4)	08 Jan 2021 15:44:49

**US3412243**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:34:16**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:35:05
User entered 'I'	System	08 Jan 2021 15:44:49



**US3412243**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:34:16**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:35:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered 'Yes (Y)'	Mason Urban (b) (4)	08 Feb 2021 18:53:02

**US3412243**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:34:16**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:35:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered '8 Feb 2021'	Mason Urban (b) (4)	08 Feb 2021 18:53:02

US3412243

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:34:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:35:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	08 Feb 2021 18:53:02

**US3412243**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:34:16**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:35:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered empty.	Mason Urban (b) (4)	08 Feb 2021 18:53:02

**US3412243**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:34:16**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:35:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered 'Yes (Y)'	Mason Urban (b) (4)	08 Feb 2021 18:53:14

**US3412243**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:34:16**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:35:05
User entered 'I'	System	08 Feb 2021 18:53:14

**US3412243**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:34:16**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:40:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	04 Mar 2021 20:10:55

**US3412243**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:34:16**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:40:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered '04 Mar 2021'	Andrea Newlands (b) (4)	04 Mar 2021 20:10:55



US3412243

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:16

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:40:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered 'Clinic (Clinic)'	Andrea Newlands (b) (4)	04 Mar 2021 20:10:55

**US3412243**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:34:16**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:40:02
User entered 'VISIT4'	System	04 Mar 2021 20:10:55

**US3412243**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:34:16**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:40:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:41:27

**US3412243**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:34:16**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:40:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered '04 Mar 2021'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:41:27

**US3412243**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:34:16**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:40:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered '10:56'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:41:27

**US3412243**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:34:16**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:40:02
User entered '04 Mar 2021 10:56'	System	31 Mar 2021 19:41:27

US3412243

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:40:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered '36.4' C	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:41:27

**US3412243**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:34:16**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:40:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:41:27



**US3412243**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:34:16**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:40:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:41:27

**US3412243**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:34:16**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:40:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered '110'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:41:27

**US3412243**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:34:16**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:40:02
User entered 'bpm'	System	31 Mar 2021 19:41:27

US3412243

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:40:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered '17'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:41:27

**US3412243**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:34:16**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:40:02
User entered 'breaths/min'	System	31 Mar 2021 19:41:27

US3412243

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:40:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered '126'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:41:27

**US3412243**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:34:16**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:40:02
User entered 'mmHg'	System	31 Mar 2021 19:41:27

US3412243

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:40:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered '90'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:41:27



**US3412243**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:34:16**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:40:02
User entered 'mmHg'	System	31 Mar 2021 19:41:27

US3412243

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:34:16

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:40:02

**US3412243**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:34:16**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:40:02

US3412243

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:40:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered 'Yes (Y)' reason for change: Data Entry Error	Andrea Newlands (b) (4)	04 Mar 2021 20:15:02
User entered 'No (N)'	Andrea Newlands (b) (4)	04 Mar 2021 20:14:44

US3412243

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:40:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered '04 Mar 2021' reason for change: Data Entry Error	Andrea Newlands (b) (4)	04 Mar 2021 20:15:02
User entered empty.	Andrea Newlands (b) (4)	04 Mar 2021 20:14:44

**US3412243**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:34:16**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:40:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	04 Mar 2021 20:15:25

US3412243

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:16

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:40:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered '04 Mar 2021'	Andrea Newlands (b) (4)	04 Mar 2021 20:15:25

**US3412243**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:34:16**

**Collection time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:40:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered '10:37'	Andrea Newlands (b) (4)	04 Mar 2021 20:15:25



**US3412243**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:34:16**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:40:02
User entered '04 Mar 2021 10:37'	System	04 Mar 2021 20:15:25

**US3412243**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:34:16**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:40:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	04 Mar 2021 20:15:41

**US3412243**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:34:16**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:40:02
User entered 'I'	System	04 Mar 2021 20:15:41

**US3412243**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:34:16**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Apr 2021 14:33:12

**US3412243**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:34:16**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered '9 Apr 2021'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:33:12

**US3412243**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:34:16**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:33:12

**US3412243**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:34:16**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:33:12

US3412243

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 14:33:15



**US3412243**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:34:16**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Apr 2021 14:33:15

**US3412243**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:34:16**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	04 Mar 2021 20:20:33

**US3412243**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:34:16**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered '04 Mar 2021'	Andrea Newlands (b) (4)	04 Mar 2021 20:20:33

US3412243

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:34:16

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered 'Clinic (Clinic)'	Andrea Newlands (b) (4)	04 Mar 2021 20:20:33

**US3412243**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:34:16**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02
User entered 'UNBLND_DECIDE'	System	04 Mar 2021 20:20:33

US3412243

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:34:16

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered '04 Mar 2021' reason for change: Data Entry Error	Andrea Newlands (b) (4)	24 Mar 2021 19:43:31
User entered '14 Mar 2021' reason for change: Data Entry Error	Andrea Newlands (b) (4)	24 Mar 2021 19:43:27
User entered '13 Jan 2021'	Andrea Newlands (b) (4)	04 Mar 2021 20:20:53

**US3412243**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:34:16**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered '0'	Andrea Newlands (b) (4)	24 Mar 2021 19:43:27
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:38:50

**US3412243**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:34:16**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	04 Mar 2021 20:20:53



US3412243

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:34:16

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User closed query 'please complete' (Site from CRA).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:54:14
Query 'please complete' answered with 'updated' (Site from CRA).	Andrea Newlands (b) (4)	24 Mar 2021 19:43:34
User entered 'Amendment 6 or later (Amendment 6 or later)'	Andrea Newlands (b) (4)	24 Mar 2021 19:43:27
User opened query 'please complete' (Site from CRA).	(b) (4), (b) (6)	11 Mar 2021 14:57:36
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:38:50

US3412243

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:34:16

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User closed query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	(b) (4)	
Query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' answered by data change (Site from System).	System	24 Mar 2021 19:43:31
User opened query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	System	24 Mar 2021 19:43:31
User entered '04 Mar 2021'	System	24 Mar 2021 19:43:27
	Andrea Newlands (b) (4)	04 Mar 2021 20:20:53
	(b) (4)	

US3412243

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:34:16

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered 'Placebo (Placebo)'	Andrea Newlands (b) (4)	04 Mar 2021 20:20:53

**US3412243**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:34:16**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered 'Placebo (Placebo)'	Andrea Newlands (b) (4)	04 Mar 2021 20:20:53

**US3412243**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:34:16**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered 'Placebo (Placebo)'	Andrea Newlands (b) (4)	04 Mar 2021 20:20:53

**US3412243**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:34:16**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	04 Mar 2021 20:20:53

**US3412243**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:34:16**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02
User entered '1'	System	04 Mar 2021 20:20:53

**US3412243**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:34:16**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02
User entered 'I'	System	04 Mar 2021 20:20:53



US3412243

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:34:16

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered '144' cm	Andrea Newlands (b) (4)	04 Mar 2021 20:22:30

US3412243

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:34:16

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered '83.6' kg	Andrea Newlands (b) (4)	04 Mar 2021 20:22:30

US3412243

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:34:16

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02
User entered '40.31636'	System	04 Mar 2021 20:22:30
DataPoint set to visible.	System	04 Mar 2021 20:20:53

US3412243

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:34:16

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered '144' cm	Andrea Newlands (b) (4)	04 Mar 2021 20:22:30

US3412243

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:34:16

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered '83.6' kg	Andrea Newlands (b) (4)	04 Mar 2021 20:22:30

**US3412243**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 17:34:16**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02
User entered '40.31636'	System	04 Mar 2021 20:22:30
DataPoint set to visible.	System	04 Mar 2021 20:20:53

US3412243

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02
User accepted default value 'Pre-Dose (PREDOSE)'	Andrea Newlands (b) (4)	04 Mar 2021 20:22:30

US3412243

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	04 Mar 2021 20:22:30



US3412243

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:16

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User closed query 'The Collection Date is before the Date of updated Informed Consent. Please review and reconcile.' (Site from System).	(b) (4)	24 Mar 2021 19:43:31
User opened query 'The Collection Date is before the Date of updated Informed Consent. Please review and reconcile.' (Site from System).	System	24 Mar 2021 19:43:27
User entered '04 Mar 2021'	Andrea Newlands (b) (4)	04 Mar 2021 20:22:30
	(b) (4)	

**US3412243**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:34:16**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered '10:56'	Andrea Newlands (b) (4)	04 Mar 2021 20:22:30

**US3412243**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:34:16**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02
User entered '04 Mar 2021 10:56'	System	04 Mar 2021 20:22:30

US3412243

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered '36.4' C	Andrea Newlands (b) (4)	04 Mar 2021 20:22:30

US3412243

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered 'Oral (Oral)'	Andrea Newlands (b) (4)	04 Mar 2021 20:22:30

**US3412243**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:34:16**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered empty.	Andrea Newlands (b) (4)	04 Mar 2021 20:22:30

**US3412243**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:34:16**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered '110'	Andrea Newlands (b) (4)	04 Mar 2021 20:22:30

**US3412243**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:34:16**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02
User entered 'bpm'	System	04 Mar 2021 20:22:30



US3412243

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered '17'	Andrea Newlands (b) (4)	04 Mar 2021 20:22:30

US3412243

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02
User entered 'breaths/min'	System	04 Mar 2021 20:22:30

US3412243

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered '126'	Andrea Newlands (b) (4)	04 Mar 2021 20:22:30

**US3412243**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:34:16**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02
User entered 'mmHg'	System	04 Mar 2021 20:22:30

US3412243

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered '90'	Andrea Newlands (b) (4)	04 Mar 2021 20:22:30

**US3412243**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:34:16**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02
User entered 'mmHg'	System	04 Mar 2021 20:22:30

US3412243

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:34:16

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered '144' cm	Andrea Newlands (b) (4)	04 Mar 2021 20:22:30

US3412243

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:34:16

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered '83.6' kg	Andrea Newlands (b) (4)	04 Mar 2021 20:22:30



**US3412243**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 17:34:16**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02
User entered '40.31636'	System	04 Mar 2021 20:22:30
DataPoint set to visible.	System	04 Mar 2021 20:20:53

**US3412243**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:34:16**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02

**US3412243**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:34:16**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02

US3412243

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02

**US3412243**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:34:16**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02

US3412243

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:16

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02

US3412243

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02

**US3412243**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:34:16**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02



**US3412243**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:34:16**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02

**US3412243**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:34:16**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02

**US3412243**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:34:16**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02

US3412243

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02

**US3412243**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:34:16**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02

**US3412243**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:34:16**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02

**US3412243**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:34:16**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02

US3412243

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02



**US3412243**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:34:16**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02

US3412243

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	04 Mar 2021 20:22:55

US3412243

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User closed query 'The physical examination date is before the Date of updated Informed Consent. Please review and reconcile.' (Site from System).	(b) (4)	24 Mar 2021 19:43:31
User opened query 'The physical examination date is before the Date of updated Informed Consent. Please review and reconcile.' (Site from System).	System	24 Mar 2021 19:43:27
User entered '04 Mar 2021'	Andrea Newlands (b) (4)	04 Mar 2021 20:22:55
	(b) (4)	

US3412243

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:16

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	04 Mar 2021 20:23:15

**US3412243**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:34:16**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered empty.	Andrea Newlands (b) (4)	04 Mar 2021 20:23:15

US3412243

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:16

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered empty.	Andrea Newlands (b) (4)	04 Mar 2021 20:23:15

US3412243

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:16

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02
User entered 'mRNA-1273'	System	04 Mar 2021 20:23:15
DataPoint set to visible.	System	04 Mar 2021 20:20:53

US3412243

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:16

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User closed query 'Start Date is prior to updated ICF Date. Please verify and reconcile.' (Site from System).	(b) (4)	24 Mar 2021 19:43:31
User opened query 'Start Date is prior to updated ICF Date. Please verify and reconcile.' (Site from System).		24 Mar 2021 19:43:27
User entered '04 Mar 2021'	Andrea Newlands (b) (4)	04 Mar 2021 20:23:15
	(b) (4)	



US3412243

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:16

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered '11:50'	Andrea Newlands (b) (4)	04 Mar 2021 20:23:15

**US3412243**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:34:16**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02
User entered '04 Mar 2021 11:50'	System	04 Mar 2021 20:23:15

US3412243

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:16

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered 'Left Arm (LEFT ARM)'	Andrea Newlands (b) (4)	04 Mar 2021 20:23:15

**US3412243**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:34:16**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02
User entered 'ONCE'	System	04 Mar 2021 20:23:15

US3412243

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:16

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02
User entered 'INTRAMUSCULAR'	System	04 Mar 2021 20:23:15

US3412243

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	04 Mar 2021 20:21:06

US3412243

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:34:16

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User closed query 'The Collection Date is before the Date of Updated Informed Consent. Please review and reconcile.' (Site from System).	(b) (4)	24 Mar 2021 19:43:31
User opened query 'The Collection Date is before the Date of Updated Informed Consent. Please review and reconcile.' (Site from System).	System	24 Mar 2021 19:43:27
User entered '04 Mar 2021'	Andrea Newlands (b) (4)	04 Mar 2021 20:21:06
	(b) (4)	

**US3412243**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:34:16**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered '10:37'	Andrea Newlands (b) (4)	04 Mar 2021 20:21:06



**US3412243**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:34:16**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02
User entered '04 Mar 2021 10:37'	System	04 Mar 2021 20:21:06

US3412243

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:34:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	04 Mar 2021 20:21:15

US3412243

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:34:16

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User closed query 'The Collection Date is before the Date of Updated Informed consent. Please review and reconcile.' (Site from System).	(b) (4)	24 Mar 2021 19:43:31
User opened query 'The Collection Date is before the Date of Updated Informed consent. Please review and reconcile.' (Site from System).	System	24 Mar 2021 19:43:27
User entered '04 Mar 2021'	Andrea Newlands (b) (4)	04 Mar 2021 20:21:15

**US3412243**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:34:16**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered '10:38'	Andrea Newlands (b) (4)	04 Mar 2021 20:21:15

**US3412243**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:34:16**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02
User entered '04 Mar 2021 10:38'	System	04 Mar 2021 20:21:15

US3412243

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:34:16

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	04 Mar 2021 20:21:20

**US3412243**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:34:16**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:18:02
User entered 'I'	System	04 Mar 2021 20:21:20

**US3412243**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:34:16**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:42:29



**US3412243**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:34:16**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:42:29

**US3412243**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:34:16**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:42:29

**US3412243**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:34:16**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:42:29

**US3412243**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:34:16**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 19:42:33

**US3412243**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:34:16**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	31 Mar 2021 19:42:33

**US3412243**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:34:16**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	31 Mar 2021 19:42:33
DataPoint set to visible.	System	31 Mar 2021 19:42:33

**US3412243**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:34:16**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Apr 2021 20:57:20

**US3412243**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:34:16**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
	(b) (4)	
User entered '5 Apr 2021'	(b) (4), (b) (6)	05 Apr 2021 20:57:20



**US3412243**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:34:16**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 20:57:20

**US3412243**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:34:16**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD29'	System	05 Apr 2021 20:57:20

**US3412243**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:34:16**

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	05 Apr 2021 20:57:54

US3412243

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 20:57:54

US3412243

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered '5 Apr 2021'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 20:57:54

**US3412243**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:34:16**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered '12:06'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 20:57:54

**US3412243**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:34:16**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '5 Apr 2021 12:06'	System	05 Apr 2021 20:57:54

US3412243

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:16

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	05 Apr 2021 20:58:22
Query 'Data is required. Please provide.' answered by System data change (Site from System).		05 Apr 2021 20:58:22
User entered '36.7' C reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 20:58:22
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Apr 2021 20:57:54
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 20:57:54



**US3412243**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:34:16**

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 20:58:22
User entered empty.		05 Apr 2021 20:57:54

**US3412243**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:34:16**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 20:57:54

US3412243

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	05 Apr 2021 20:58:22
Query 'Data is required. Please provide.' answered by System data change (Site from System).		05 Apr 2021 20:58:22
User entered '88' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 20:58:22
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Apr 2021 20:57:54
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 20:57:54

**US3412243**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:34:16**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	05 Apr 2021 20:58:22
User entered empty.	System	05 Apr 2021 20:57:54

US3412243

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	05 Apr 2021 20:58:22
Query 'Data is required. Please provide.' answered by System data change (Site from System).		05 Apr 2021 20:58:22
User entered '16' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 20:58:22
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Apr 2021 20:57:54
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 20:57:54

**US3412243**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:34:16**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	05 Apr 2021 20:58:22
User entered empty.	System	05 Apr 2021 20:57:54

US3412243

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:16

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	05 Apr 2021 20:58:22
Query 'Data is required. Please provide.' answered by System data change (Site from System).		05 Apr 2021 20:58:22
User entered '130' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 20:58:22
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Apr 2021 20:57:54
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 20:57:54

**US3412243**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:34:16**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Apr 2021 20:58:22
User entered empty.	System	05 Apr 2021 20:57:54



US3412243

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:34:16

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	05 Apr 2021 20:58:22
Query 'Data is required. Please provide.' answered by System data change (Site from System).		05 Apr 2021 20:58:22
User entered '92' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 20:58:22
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Apr 2021 20:57:54
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 20:57:54

**US3412243**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:34:16**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Apr 2021 20:58:22
User entered empty.	System	05 Apr 2021 20:57:54

US3412243

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:16

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	05 Apr 2021 20:57:54

**US3412243**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:34:16**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 20:57:54

US3412243

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered '5 Apr 2021'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 20:57:54

**US3412243**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:34:16**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered '13:34'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 20:57:54

**US3412243**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:34:16**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '5 Apr 2021 13:34'	System	05 Apr 2021 20:57:54

US3412243

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:16

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	05 Apr 2021 20:58:54
Query 'Data is required. Please provide.' answered by System data change (Site from System).		05 Apr 2021 20:58:54
User entered '36.6' C reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 20:58:54
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Apr 2021 20:57:54
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 20:57:54



US3412243

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:16

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 20:58:54
User entered empty.		05 Apr 2021 20:57:54

**US3412243**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:34:16**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 20:57:54

US3412243

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	05 Apr 2021 20:58:54
Query 'Data is required. Please provide.' answered by System data change (Site from System).		05 Apr 2021 20:58:54
User entered '81' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 20:58:54
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Apr 2021 20:57:54
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 20:57:54

**US3412243**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:34:16**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	05 Apr 2021 20:58:54
User entered empty.	System	05 Apr 2021 20:57:54

US3412243

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:16

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	05 Apr 2021 20:58:54
Query 'Data is required. Please provide.' answered by System data change (Site from System).		05 Apr 2021 20:58:54
User entered '16' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 20:58:54
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Apr 2021 20:57:54
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 20:57:54

**US3412243**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:34:16**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	05 Apr 2021 20:58:54
User entered empty.	System	05 Apr 2021 20:57:54

US3412243

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:16

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	05 Apr 2021 20:58:54
Query 'Data is required. Please provide.' answered by System data change (Site from System).		05 Apr 2021 20:58:54
User entered '130' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 20:58:54
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Apr 2021 20:57:54
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 20:57:54

**US3412243**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:34:16**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Apr 2021 20:58:54
User entered empty.	System	05 Apr 2021 20:57:54



US3412243

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:34:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	05 Apr 2021 20:58:54
Query 'Data is required. Please provide.' answered by System data change (Site from System).		05 Apr 2021 20:58:54
User entered '90' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 20:58:54
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Apr 2021 20:57:54
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 20:57:54

**US3412243**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:34:16**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Apr 2021 20:58:54
User entered empty.	System	05 Apr 2021 20:57:54

**US3412243**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:34:16**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 20:59:20

US3412243

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:34:16

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 20:59:20

US3412243

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:16

[Was study treatment given?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 20:59:46

US3412243

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:16

[If No, reason not given](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 20:59:46

US3412243

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:16

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 20:59:46

**US3412243**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:34:16**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
User entered 'mRNA-1273'	System	05 Apr 2021 20:59:46
DataPoint set to visible.	System	31 Mar 2021 19:42:33



US3412243

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:16

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered '5 Apr 2021'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 20:59:46

**US3412243**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:34:16**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered '12:56'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 20:59:46

**US3412243**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:34:16**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '5 Apr 2021 12:56'	System	05 Apr 2021 20:59:46

US3412243

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:34:16

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 20:59:46

**US3412243**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:34:16**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	05 Apr 2021 20:59:46

**US3412243**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:34:16**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	05 Apr 2021 20:59:46

**US3412243**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:34:16**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Apr 2021 20:59:51

**US3412243**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:34:16**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Apr 2021 20:59:51



US3412243

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:34:16

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:41
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:37:33
User entered 'Yes (Y)' reason for change: Data Entry Error	Steven Anderson (b) (4)	04 Mar 2021 19:35:11
User entered 'No (N)'	Jacob sekinger (b) (4)	24 Sep 2020 13:43:17

**US3412243**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:34:16**

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:44:54
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:10:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:40:07
User entered 'USA-US061-2021-mRNA-1273-P301000012'	System	05 Mar 2021 16:54:38
User entered 'New'	(b) (4), (b) (6)	05 Mar 2021 16:54:38

US3412243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:16

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:44:54
User closed query 'Please correct spelling' (Site from CRA).	(b) (4)	22 Apr 2021 14:44:36
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthritis, PT: Osteoarthritis, LLT: Osteoarthritis aggravated - version MedDRA\\23.0.	Coder Import (b) (4)	22 Apr 2021 13:09:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Apr 2021 13:09:58
Query 'Please correct spelling' answered with 'information has been updated' (Site from CRA).	(b) (4), (b) (6)	22 Apr 2021 13:09:39
Data point term sent to Coder	System	22 Apr 2021 13:09:15
Coding entries removed.	(b) (4), (b) (6)	22 Apr 2021 13:09:12
Signature has been broken.	(b) (4)	22 Apr 2021 13:09:12
User entered 'WORSENING OF Osteoarthritis' reason for change: Data Entry Error	(b) (4)	22 Apr 2021 13:09:12
User opened query 'Please correct spelling' (Site from CRA).	(b) (4)	20 Apr 2021 20:34:30
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:10:50
User closed query 'PV Query: Please confirm that the total left knee replacement surgery was scheduled prior to onset of study. If yes, please reassess validity and/or seriousness of the event.' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 17:39:41
Query 'PV Query: Please confirm that the total left knee replacement surgery was scheduled prior to onset of study. If yes, please reassess validity and/or seriousness of the event.' answered with 'surgery was scheduled prior to study enrollment' (Site from Safety).	(b) (4)	05 Apr 2021 16:39:50
User opened query 'PV Query: Please confirm that the total left knee replacement surgery was scheduled prior to onset of study. If yes, please reassess validity and/or seriousness of the event.' (Site from Safety).	(b) (4)	10 Mar 2021 19:44:52
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthritis, PT: Osteoarthritis, LLT: Osteoarthritis aggravated - version MedDRA\\23.0.	Coder Import (b) (4)	06 Mar 2021 12:25:03

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:16

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	06 Mar 2021 12:25:03
Data point term sent to Coder	(b) (4) System	04 Mar 2021 19:39:35
User entered 'Worsening of ostoarthritis'	Steven Anderson (b) (4)	04 Mar 2021 19:39:22
	(b) (4)	

US3412243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:16

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:36:20
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:10:50
	(b) (4)	
User entered 'Yes (Y)'	Steven Anderson (b) (4)	04 Mar 2021 19:39:22
	(b) (4)	

US3412243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:16

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:36:22
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:10:50
	(b) (4)	
User entered 'No (N)'	Steven Anderson (b) (4)	04 Mar 2021 19:39:22
	(b) (4)	

US3412243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:16

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:36:24
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:10:50
	(b) (4)	
User entered 'No (N)'	Steven Anderson (b) (4)	04 Mar 2021 19:39:22
	(b) (4)	

US3412243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:38:32
DataPoint Un-verified.		20 Apr 2021 20:38:30
DataPoint Verified.		20 Apr 2021 20:36:26
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:10:50
User entered '15 Oct 2020'	(b) (4)	
	Steven Anderson (b) (4)	04 Mar 2021 19:39:22
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:16

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:38:33
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:10:50
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	04 Mar 2021 19:39:22
	(b) (4)	

**US3412243**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:34:16**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Mar 2021 19:39:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:16

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 18:05:43
DataPoint Verified.		22 Apr 2021 14:44:54
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved' answered with 'information has been updated' (Site from Safety). Signature has been broken.		22 Apr 2021 13:13:53
		22 Apr 2021 13:09:12
User entered 'No (N)' reason for change: Data Entry Error		22 Apr 2021 13:09:12
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved' (Site from Safety).		16 Apr 2021 21:17:05
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:10:50
	(b) (4)	
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.	(b) (4), (b) (6)	07 Apr 2021 05:37:54
' (Site from DM).		
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'AE is still ongoing at this time. ' (Site from DM).		05 Apr 2021 16:43:41
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.		24 Mar 2021 11:52:09
' (Site from DM).		
User entered 'Yes (Y)'	Steven Anderson (b) (4)	04 Mar 2021 19:39:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:16

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per source, AE ended on 18 Mar 2021. Please confirm and update as appropriate' (Site from CRA).	(b) (4), (b) (6)	22 Apr 2021 14:45:40
DataPoint Verified.		22 Apr 2021 14:44:54
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	22 Apr 2021 13:11:41
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	22 Apr 2021 13:11:41
Query 'Per source, AE ended on 18 Mar 2021. Please confirm and update as appropriate' answered with 'information has been updated' (Site from CRA).	(b) (4), (b) (6)	22 Apr 2021 13:10:08
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	22 Apr 2021 13:09:12
Signature has been broken.	(b) (4), (b) (6)	22 Apr 2021 13:09:12
User entered '18 Mar 2021' reason for change: Data Entry Error		22 Apr 2021 13:09:12
User opened query 'Per source, AE ended on 18 Mar 2021. Please confirm and update as appropriate' (Site from CRA).		20 Apr 2021 20:32:15
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:10:50
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	04 Mar 2021 19:39:22
	(b) (4)	

**US3412243**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:34:16**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:44:54
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:10:50
User entered empty.	Steven Anderson (b) (4)	04 Mar 2021 19:39:22

**US3412243**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:34:16**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 15:45:40
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).		10 Mar 2021 19:41:09
User entered empty.	System	04 Mar 2021 19:39:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:16

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:38:38
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:10:50
	(b) (4)	
User entered 'Grade 4 (Grade 4)'	Steven Anderson (b) (4)	04 Mar 2021 19:39:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:16

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:38:46
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:10:50
	(b) (4)	
User entered 'Yes (Y)'	Steven Anderson (b) (4)	04 Mar 2021 19:39:22
	(b) (4)	



**US3412243**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:34:16**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:44:54
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:10:50
User entered '0'	Steven Anderson (b) (4)	04 Mar 2021 19:39:22

**US3412243**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:34:16**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:44:54
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:10:50
User entered '0'	Steven Anderson (b) (4)	04 Mar 2021 19:39:22

**US3412243**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:34:16**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:44:54
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:10:50
User entered 'I'	Steven Anderson (b) (4)	04 Mar 2021 19:39:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:16

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:44:54
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:10:50
User entered '13 Jan 2021'	Steven Anderson (b) (4)	04 Mar 2021 19:39:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:16

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:44:54
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:10:50
User entered '18 Jan 2021'	Steven Anderson (b) (4)	04 Mar 2021 19:39:22

**US3412243**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:34:16**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:44:54
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:10:50
User entered 'No (N)'	Steven Anderson (b) (4)	04 Mar 2021 19:39:22

**US3412243**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:34:16**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:44:54
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:10:50
User entered empty.	Steven Anderson (b) (4)	04 Mar 2021 19:39:22

US3412243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:44:54
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:10:50
User entered '0'	Steven Anderson (b) (4)	04 Mar 2021 19:39:22



**US3412243**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:34:16**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:44:54
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:10:50
User entered '0'	Steven Anderson (b) (4)	04 Mar 2021 19:39:22

**US3412243**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:34:16**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:44:54
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:10:50
User entered '0'	Steven Anderson (b) (4)	04 Mar 2021 19:39:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:16

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:38:53
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:10:50
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Steven Anderson (b) (4)	04 Mar 2021 19:39:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:16

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:38:56
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:10:50
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Steven Anderson (b) (4)	04 Mar 2021 19:39:22
	(b) (4)	

US3412243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:16

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 20:38:59
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:10:50
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Steven Anderson (b) (4)	04 Mar 2021 19:39:22
	(b) (4)	

**US3412243**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:34:16**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:44:54
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:10:50
User entered '0'	Steven Anderson (b) (4)	04 Mar 2021 19:39:22

US3412243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:16

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:44:54
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:10:50
User closed query 'PV Query: Please provide any other treatment given for the event including medical intervention and/or surgical treatments. Please add any additional treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 17:39:52
Query 'PV Query: Please provide any other treatment given for the event including medical intervention and/or surgical treatments. Please add any additional treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' answered with 'INFORMATION HAS BEEN UPDATED' (Site from Safety).		05 Apr 2021 16:42:46
User entered '1' reason for change: Data Entry Error		05 Apr 2021 16:40:48
User opened query 'PV Query: Please provide any other treatment given for the event including medical intervention and/or surgical treatments. Please add any additional treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' (Site from Safety).		10 Mar 2021 19:42:04
User entered '0'	Steven Anderson (b) (4)	04 Mar 2021 19:39:22

**US3412243**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:34:16**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:44:54
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:10:50
User entered 'I'	Steven Anderson (b) (4)	04 Mar 2021 19:39:22



US3412243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:16

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:44:54
Signature has been broken.		22 Apr 2021 13:11:41
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error		22 Apr 2021 13:11:41
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:10:50
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:40:02
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'Knee pain is stable' (Site from Safety).		05 Apr 2021 16:42:15
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error		25 Mar 2021 18:40:38
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).		10 Mar 2021 19:41:43
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Steven Anderson (b) (4) (b) (4)	04 Mar 2021 19:39:22

**US3412243**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:34:16**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:44:54
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:10:50
User entered empty.	Steven Anderson (b) (4)	04 Mar 2021 19:39:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:16

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:44:54
User opened query 'PV Query: Please provide any other treatment given for the event including medical intervention and/or surgical treatments. Please add any additional treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).		16 Apr 2021 21:17:13
' (Site from Safety). User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' (Site from Safety). User signature succeeded.		16 Apr 2021 21:16:42
	Richard Powell (b) (4)	12 Apr 2021 14:10:50
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety). User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety). Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'no results are available ' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 17:39:58
		06 Apr 2021 17:39:55
		05 Apr 2021 16:44:08

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US3412243

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:34:16

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'testing was negative' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 16:41:35
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).		10 Mar 2021 19:41:26
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).		10 Mar 2021 19:40:47
User entered 'Subject presented 04-Mar-2021 for day 209 visit. subject expressed that she had worsening of her osteoarthritis and that it caused her to have a left total knee replacement surgery in which she was hospitalized for 5 days for recovery. subject states this was scheduled prior to this study. knee pain is better since surgery, but not resolved.'	Steven Anderson (b) (4)	04 Mar 2021 19:39:22

**US3412243**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:34:16**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Mar 2021 19:39:22

**US3412243**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:34:16**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Mar 2021 19:39:22

**US3412243**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:34:16**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	04 Mar 2021 19:39:22

**US3412243**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 09 Jun 2021 17:34:16**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:41
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:41:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:54:39



US3412243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
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.	(b) (4) Coder Import (b) (4)	20 Aug 2020 17:58:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Aug 2020 17:58:15
Data point term sent to Coder	System	20 Aug 2020 17:56:14
User entered 'ALBUTEROL'	(b) (4), (b) (6)	20 Aug 2020 17:55:17

**US3412243**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:34:16**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:55:17

**US3412243**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:34:16**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered 'ASTHMA'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:55:17

US3412243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of puff count. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Oct 2020 10:42:30
Query 'Per DM CLR: Please provide the actual dose for this medication instead of puff count. Update the Dose and Dose Unit fields as appropriate.' answered with 'UPDATED' (Site from DM).	Mylene Asmar-Rios (b) (4)	15 Oct 2020 18:43:51
User entered '90' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	15 Oct 2020 18:43:35
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of puff count. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 04:11:28
User entered '2'		20 Aug 2020 17:55:17

**US3412243**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:34:16**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
	(b) (4)	
User entered 'ug (ug)' reason for change: Data Entry	Mylene Asmar-Rios	15 Oct 2020 18:43:35
Error	(b) (4)	
User entered 'puff (PUFF)'	(b) (4), (b) (6)	20 Aug 2020 17:55:17

US3412243

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:34:16**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:55:17

**US3412243**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:34:16**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:55:17

US3412243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:55:17



US3412243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:55:17

US3412243

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:34:16**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:55:17

US3412243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
	(b) (4)	
Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version.		21 Aug 2020 04:31:33
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'NA' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 18:12:24
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 17:55:17
User entered 'UN UNK 1975'	(b) (4), (b) (6)	20 Aug 2020 17:55:17

**US3412243**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:34:16**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:55:17

**US3412243**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:34:16**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:55:17

**US3412243**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:34:16**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:55:17

US3412243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:34:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:55:17

**US3412243**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:34:16**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 17:55:17



**US3412243**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:34:16**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 17:55:17

**US3412243**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:34:16**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 17:55:17

US3412243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	20 Aug 2020 17:57:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 17:57:27
Data point term sent to Coder	System	20 Aug 2020 17:56:16
User entered 'ATORVASTATIN'	(b) (4), (b) (6)	20 Aug 2020 17:55:53

US3412243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:55:53

**US3412243**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:34:16**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered 'HYPERLIPIDEMIA'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:55:53

US3412243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered '25'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:55:53

US3412243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:55:53

US3412243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:55:53



US3412243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:55:53

US3412243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:55:53

**US3412243**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:34:16**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:55:53

US3412243

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:34:16**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:55:53

US3412243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:34:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
	(b) (4)	
Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version.		21 Aug 2020 04:31:33
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'NA' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 18:12:29
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 17:55:53
User entered 'UN UNK 2017'	(b) (4), (b) (6)	20 Aug 2020 17:55:53

**US3412243**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:34:16**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:55:53

**US3412243**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:34:16**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:55:53

US3412243

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:34:16**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:55:53



US3412243

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:34:16**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:55:53

**US3412243**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:34:16**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 17:55:53

**US3412243**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:34:16**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 17:55:53

**US3412243**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:34:16**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 17:55:53

US3412243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Oct 2020 23:48:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Oct 2020 23:48:25
Data point term sent to Coder	System	15 Oct 2020 18:45:13
Coding entries removed.	Mylene Asmar-Rios	15 Oct 2020 18:44:18
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Aug 2020 16:37:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Aug 2020 16:37:16
Data point term sent to Coder	System	22 Aug 2020 16:31:27
Query 'CDM-Coding: The trade name can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term.	Coder Import (b) (4)	22 Aug 2020 16:31:14
' canceled (Site from System).		
User opened query 'CDM-Coding: The trade name can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term.	Coder Import (b) (4)	22 Aug 2020 10:06:08
' (Site from System).		

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	20 Aug 2020 17:59:22
User entered 'FLONASE'	(b) (4), (b) (6)	20 Aug 2020 17:58:33

**US3412243**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:34:16**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:58:33

US3412243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User closed query 'please correct spelling perennial' (Site from CRA).	(b) (4) (b) (4), (b) (6)	11 Mar 2021 01:25:45
Query 'please correct spelling perennial' answered with 'UPDATED' (Site from CRA).	Mylene Asmar-Rios (b) (4)	15 Oct 2020 18:44:27
User entered 'PERENNIAL ALLERGIC RHINITIS' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	15 Oct 2020 18:44:18
User opened query 'please correct spelling perennial' (Site from CRA).	(b) (4), (b) (6)	25 Sep 2020 22:18:20
User entered 'PERENIAL ALLERGIC RHINITIS'		20 Aug 2020 17:58:33



US3412243

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:34:16**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered '50'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:58:33

US3412243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered 'ug (ug)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:58:33

US3412243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:58:33

**US3412243**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:34:16**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:58:33

US3412243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:58:33

**US3412243**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:34:16**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered 'Nasal (NASAL)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:58:33

US3412243

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:34:16**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:58:33

US3412243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
	(b) (4)	
Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version.		21 Aug 2020 04:31:33
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'NA' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 18:12:35
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 17:58:33
User entered 'UN UNK 2016'	(b) (4), (b) (6)	20 Aug 2020 17:58:33



US3412243

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:34:16**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:58:33

**US3412243**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:34:16**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:58:33

US3412243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:34:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:58:33

US3412243

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:34:16**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:58:33

**US3412243**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:34:16**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 17:58:33

**US3412243**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:34:16**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 17:58:33

**US3412243**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:34:16**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 17:58:33

US3412243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:34:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	20 Aug 2020 18:00:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 18:00:20
Data point term sent to Coder	System	20 Aug 2020 17:59:22
User entered 'METFORMIN'	(b) (4), (b) (6)	20 Aug 2020 17:59:05



**US3412243**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:34:16**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:59:05

**US3412243**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:34:16**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered 'DIABETES TYPE 2'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:59:05

US3412243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:34:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered '500'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:59:05

**US3412243**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:34:16**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:59:05

US3412243

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:34:16**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:59:05

**US3412243**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:34:16**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:59:05

US3412243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:34:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:59:05

**US3412243**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:34:16**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:59:05



US3412243

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:34:16**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:59:05

US3412243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:34:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
	(b) (4)	
Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version.		21 Aug 2020 04:31:33
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'NA' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 18:12:40
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 17:59:05
User entered 'UN UNK 2016'	(b) (4), (b) (6)	20 Aug 2020 17:59:05

**US3412243**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:34:16**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:59:05

US3412243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:34:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:59:05

US3412243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:34:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:59:05

US3412243

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:34:16**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:59:05

**US3412243**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:34:16**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 17:59:05

**US3412243**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:34:16**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 17:59:05



**US3412243**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:34:16**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 17:59:05

US3412243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	20 Aug 2020 18:01:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 18:01:24
Data point term sent to Coder	System	20 Aug 2020 18:00:24
User entered 'OMEPRAZOLE'	(b) (4), (b) (6)	20 Aug 2020 17:59:56

**US3412243**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:34:16**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:59:56

**US3412243**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:34:16**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered 'Gastroesophageal reflux disease'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:59:56

**US3412243**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:34:16**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered '20'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:59:56

US3412243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:59:56

**US3412243**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:34:16**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:59:56

US3412243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:59:56



US3412243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:59:56

**US3412243**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:34:16**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:59:56

US3412243

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:34:16**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:59:56

US3412243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
	(b) (4)	
Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version.		21 Aug 2020 04:31:33
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'NA' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 18:12:46
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 17:59:56
User entered 'UN UNK 2017'	(b) (4), (b) (6)	20 Aug 2020 17:59:56

**US3412243**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:34:16**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:59:56

**US3412243**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:34:16**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:59:56

**US3412243**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:34:16**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:59:56

US3412243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:34:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 17:59:56



**US3412243**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:34:16**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 17:59:56

**US3412243**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:34:16**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 17:59:56

**US3412243**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:34:16**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 17:59:56

US3412243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:34:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User closed query 'please correct spelling - singulair' (Site from CRA).	(b) (4) (b) (4), (b) (6)	11 Mar 2021 01:26:04
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST SODIUM, PRODUCTSYNONYM: SINGULAIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 18:47:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 18:47:36
Data point term sent to Coder	System	15 Oct 2020 18:46:14
Query 'please correct spelling - singulair' answered with 'UPDATED' (Site from CRA).	Mylene Asmar-Rios (b) (4)	15 Oct 2020 18:45:38
Coding entries removed.	Mylene Asmar-Rios (b) (4)	15 Oct 2020 18:45:26
User entered 'SINGULAIR' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	15 Oct 2020 18:45:26
User opened query 'please correct spelling - singulair' (Site from CRA).	(b) (4), (b) (6)	25 Sep 2020 22:18:49
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST SODIUM, PRODUCTSYNONYM: SINGULAIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 18:02:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 18:02:17
Data point term sent to Coder	System	20 Aug 2020 18:01:25
User entered 'SINGULAR'	(b) (4), (b) (6)	20 Aug 2020 18:00:34

**US3412243**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:34:16**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:00:34

**US3412243**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:34:16**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered 'ASTHMA'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:00:34

**US3412243**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:34:16**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered '10'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:00:34

US3412243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:34:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:00:34



**US3412243**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:34:16**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:00:34

**US3412243**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:34:16**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:00:34

US3412243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:34:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:00:34

**US3412243**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:34:16**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:00:34

US3412243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:34:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:00:34

US3412243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:34:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
	(b) (4)	
Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version.		21 Aug 2020 04:31:33
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'NA' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 18:12:51
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 18:00:34
User entered 'UN UNK 2016'	(b) (4), (b) (6)	20 Aug 2020 18:00:34

**US3412243**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:34:16**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:00:34

**US3412243**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:34:16**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:00:34



**US3412243**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:34:16**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:00:34

**US3412243**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:34:16**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:00:34

**US3412243**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:34:16**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 18:00:34

**US3412243**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:34:16**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 18:00:34

**US3412243**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:34:16**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 18:00:34

US3412243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:34:16

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	22 Aug 2020 14:39:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Aug 2020 14:39:17
Data point term sent to Coder	System	22 Aug 2020 14:35:13
Query 'CDM-Coding: The trade name can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term.	Coder Import (b) (4) (b) (4)	22 Aug 2020 14:35:12
' canceled (Site from System).		
User opened query 'CDM-Coding: The trade name can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term.	Coder Import (b) (4) (b) (4)	21 Aug 2020 06:52:09
' (Site from System).		
Data point term sent to Coder	System	20 Aug 2020 18:01:27
User entered 'ZYRTEC'	(b) (4), (b) (6)	20 Aug 2020 18:01:25

US3412243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:34:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:01:25

**US3412243**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:34:16**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered 'PERENNIAL ALLERGIC RHINITIS'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:01:25



**US3412243**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:34:16**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered '10'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:01:25

US3412243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:34:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:01:25

US3412243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:34:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:01:25

**US3412243**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:34:16**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:01:25

US3412243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:34:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:01:25

**US3412243**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:34:16**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:01:25

US3412243

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:34:16**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:01:25

US3412243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:34:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
	(b) (4)	
Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version.		21 Aug 2020 04:31:33
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'NA' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 18:12:58
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 18:01:25
User entered 'UN UNK 2016'	(b) (4), (b) (6)	20 Aug 2020 18:01:25



**US3412243**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:34:16**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:01:25

**US3412243**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:34:16**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:01:25

**US3412243**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:34:16**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:01:25

US3412243

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:34:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:23:20
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 18:01:25

**US3412243**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:34:16**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 18:01:25

**US3412243**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:34:16**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 18:01:25

**US3412243**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:34:16**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 18:01:25

**US3412243**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 09 Jun 2021 17:34:16**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:41
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:41:13
User entered 'Yes (Y)' reason for change: Data Entry Error	Steven Anderson (b) (4)	04 Mar 2021 19:40:07
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 17:54:18



US3412243

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:34:16

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:41:13
	(b) (4)	
User entered '13 Jan 2021'	Steven Anderson (b) (4)	04 Mar 2021 19:40:34
	(b) (4)	

US3412243

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:34:16

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:41:13
	(b) (4)	
User entered 'left total knee replacement'	Steven Anderson (b) (4)	04 Mar 2021 19:40:34
	(b) (4)	

US3412243

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:34:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:41:13
	(b) (4)	
User entered 'Adverse Event (AE)'	Steven Anderson (b) (4)	04 Mar 2021 19:40:34
	(b) (4)	

US3412243

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:34:16

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:41:13
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	04 Mar 2021 19:40:34
	(b) (4)	

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:54:52
User entered 'USA-US061-2021-MRNA-1273-P301000012'	System	05 Mar 2021 16:54:38

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:54:52
User entered 'Yes (Y)'	System	05 Mar 2021 16:54:38

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:54:52
User entered 'No (N)'	System	05 Mar 2021 16:54:38

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:54:52
User entered 'No (N)'	System	05 Mar 2021 16:54:38



**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:54:52
User entered 'Yes (Y)'	System	05 Mar 2021 16:54:38

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:54:52
User entered 'No (N)'	System	05 Mar 2021 16:54:38

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:54:52
User entered 'No (N)'	System	05 Mar 2021 16:54:38

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:54:52
User entered 'No (N)'	System	05 Mar 2021 16:54:38

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:42:49
Un-reviewed for Safety.	System	26 Mar 2021 13:37:57
User entered 'Richard'	System	26 Mar 2021 13:37:57
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:54:52
User entered 'Gregory'	System	05 Mar 2021 16:54:38

US3412243

Folder: SAE USA-US061-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:42:49
Un-reviewed for Safety.	System	26 Mar 2021 13:37:57
User entered 'Powell'	System	26 Mar 2021 13:37:57
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:54:52
User entered 'Gottschlich'	System	05 Mar 2021 16:54:38

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:42:49
Un-reviewed for Safety.	System	26 Mar 2021 13:37:57
User entered empty.	System	26 Mar 2021 13:37:57
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:54:52
User entered '4260 Glendale Milford Road'	System	05 Mar 2021 16:54:38

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:42:49
Un-reviewed for Safety.	System	26 Mar 2021 13:37:57
User entered empty.	System	26 Mar 2021 13:37:57
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:54:52
User entered 'Cincinnati'	System	05 Mar 2021 16:54:38



**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:42:49
User entered 'OH'	System	26 Mar 2021 13:37:57

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:42:49
Un-reviewed for Safety.	System	26 Mar 2021 13:37:57
User entered empty.	System	26 Mar 2021 13:37:57
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:54:52
User entered '45242'	System	05 Mar 2021 16:54:38

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 13:37:48
User entered 'US'	System	05 Mar 2021 16:55:01

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	22 Apr 2021 18:07:30
User entered '3'	System	06 Apr 2021 17:43:02
User entered '2'	System	26 Mar 2021 13:37:57
User entered '1'	System	05 Mar 2021 16:55:01

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:54:52
User entered 'USA-US061-2021-MRNA-1273-P301000012'	System	05 Mar 2021 16:54:38

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:54:52
User entered 'Yes (Y)'	System	05 Mar 2021 16:54:38

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:54:52
User entered 'No (N)'	System	05 Mar 2021 16:54:38

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:54:52
User entered 'No (N)'	System	05 Mar 2021 16:54:38



**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:54:52
User entered 'Yes (Y)'	System	05 Mar 2021 16:54:38

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:54:52
User entered 'No (N)'	System	05 Mar 2021 16:54:38

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:54:52
User entered 'No (N)'	System	05 Mar 2021 16:54:38

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:54:52
User entered 'No (N)'	System	05 Mar 2021 16:54:38

US3412243

Folder: SAE USA-US061-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 17:34:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:42:49
Un-reviewed for Safety.	System	26 Mar 2021 13:37:57
User entered 'Richard'	System	26 Mar 2021 13:37:57
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:54:52
User entered 'Gregory'	System	05 Mar 2021 16:54:38

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:42:49
Un-reviewed for Safety.	System	26 Mar 2021 13:37:57
User entered 'Powell'	System	26 Mar 2021 13:37:57
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:54:52
User entered 'Gottschlich'	System	05 Mar 2021 16:54:38

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:42:49
Un-reviewed for Safety.	System	26 Mar 2021 13:37:57
User entered empty.	System	26 Mar 2021 13:37:57
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:54:52
User entered '4260 Glendale Milford Road'	System	05 Mar 2021 16:54:38

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:42:49
Un-reviewed for Safety.	System	26 Mar 2021 13:37:57
User entered empty.	System	26 Mar 2021 13:37:57
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:54:52
User entered 'Cincinnati'	System	05 Mar 2021 16:54:38



**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:42:49
User entered 'OH'	System	26 Mar 2021 13:37:57

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:42:49
Un-reviewed for Safety.	System	26 Mar 2021 13:37:57
User entered empty.	System	26 Mar 2021 13:37:57
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:54:52
User entered '45242'	System	05 Mar 2021 16:54:38

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 13:37:48
User entered 'US'	System	05 Mar 2021 16:55:01

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	22 Apr 2021 18:07:30
User entered '3'	System	06 Apr 2021 17:43:02
User entered '2'	System	26 Mar 2021 13:37:57
User entered '1'	System	05 Mar 2021 16:55:01

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 17:34:16**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered '05/Mar/2021 11:54'	(b) (4) System	05 Mar 2021 16:55:01

US3412243

Folder: SAE USA-US061-2021-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:34:16

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:37:48
User entered 'I'		05 Mar 2021 16:55:01

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:54:52
User entered 'USA-US061-2021-MRNA-1273-P301000012'	System	05 Mar 2021 16:54:38

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:54:52
User entered 'Yes (Y)'	System	05 Mar 2021 16:54:38



**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:54:52
User entered 'No (N)'	System	05 Mar 2021 16:54:38

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:54:52
User entered 'No (N)'	System	05 Mar 2021 16:54:38

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:54:52
User entered 'Yes (Y)'	System	05 Mar 2021 16:54:38

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:54:52
User entered 'No (N)'	System	05 Mar 2021 16:54:38

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:54:52
User entered 'No (N)'	System	05 Mar 2021 16:54:38

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:54:52
User entered 'No (N)'	System	05 Mar 2021 16:54:38

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:42:49
Un-reviewed for Safety.	System	26 Mar 2021 13:37:57
User entered 'Richard'	System	26 Mar 2021 13:37:57
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:54:52
User entered 'Gregory'	System	05 Mar 2021 16:54:38

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:42:49
Un-reviewed for Safety.	System	26 Mar 2021 13:37:57
User entered 'Powell'	System	26 Mar 2021 13:37:57
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:54:52
User entered 'Gottschlich'	System	05 Mar 2021 16:54:38



**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:42:49
Un-reviewed for Safety.	System	26 Mar 2021 13:37:57
User entered empty.	System	26 Mar 2021 13:37:57
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:54:52
User entered '4260 Glendale Milford Road'	System	05 Mar 2021 16:54:38

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:42:49
Un-reviewed for Safety.	System	26 Mar 2021 13:37:57
User entered empty.	System	26 Mar 2021 13:37:57
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:54:52
User entered 'Cincinnati'	System	05 Mar 2021 16:54:38

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:42:49
User entered 'OH'	System	26 Mar 2021 13:37:57

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:42:49
Un-reviewed for Safety.	System	26 Mar 2021 13:37:57
User entered empty.	System	26 Mar 2021 13:37:57
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:54:52
User entered '45242'	System	05 Mar 2021 16:54:38

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 13:37:48
User entered 'US'	System	05 Mar 2021 16:55:01

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	22 Apr 2021 18:07:30
User entered '3'	System	06 Apr 2021 17:43:02
User entered '2'	System	26 Mar 2021 13:37:57
User entered '1'	System	05 Mar 2021 16:55:01

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 17:34:16**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered '26/Mar/2021 08:37'	(b) (4) System	26 Mar 2021 13:37:57

US3412243

Folder: SAE USA-US061-2021-MRNA-1273-P301000012

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:34:16

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 17:42:49
User entered 'I'		26 Mar 2021 13:37:57



**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:54:52
User entered 'USA-US061-2021-MRNA-1273-P301000012'	System	05 Mar 2021 16:54:38

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:54:52
User entered 'Yes (Y)'	System	05 Mar 2021 16:54:38

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:54:52
User entered 'No (N)'	System	05 Mar 2021 16:54:38

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:54:52
User entered 'No (N)'	System	05 Mar 2021 16:54:38

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:54:52
User entered 'Yes (Y)'	System	05 Mar 2021 16:54:38

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:54:52
User entered 'No (N)'	System	05 Mar 2021 16:54:38

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:54:52
User entered 'No (N)'	System	05 Mar 2021 16:54:38

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:54:52
User entered 'No (N)'	System	05 Mar 2021 16:54:38



**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:42:49
Un-reviewed for Safety.	System	26 Mar 2021 13:37:57
User entered 'Richard'	System	26 Mar 2021 13:37:57
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:54:52
User entered 'Gregory'	System	05 Mar 2021 16:54:38

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:42:49
Un-reviewed for Safety.	System	26 Mar 2021 13:37:57
User entered 'Powell'	System	26 Mar 2021 13:37:57
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:54:52
User entered 'Gottschlich'	System	05 Mar 2021 16:54:38

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:42:49
Un-reviewed for Safety.	System	26 Mar 2021 13:37:57
User entered empty.	System	26 Mar 2021 13:37:57
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:54:52
User entered '4260 Glendale Milford Road'	System	05 Mar 2021 16:54:38

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:42:49
Un-reviewed for Safety.	System	26 Mar 2021 13:37:57
User entered empty.	System	26 Mar 2021 13:37:57
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:54:52
User entered 'Cincinnati'	System	05 Mar 2021 16:54:38

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:42:49
User entered 'OH'	System	26 Mar 2021 13:37:57

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:42:49
Un-reviewed for Safety.	System	26 Mar 2021 13:37:57
User entered empty.	System	26 Mar 2021 13:37:57
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:54:52
User entered '45242'	System	05 Mar 2021 16:54:38

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 13:37:48
User entered 'US'	System	05 Mar 2021 16:55:01

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	22 Apr 2021 18:07:30
User entered '3'	System	06 Apr 2021 17:43:02
User entered '2'	System	26 Mar 2021 13:37:57
User entered '1'	System	05 Mar 2021 16:55:01



**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 17:34:16**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered '06/Apr/2021 13:42'	(b) (4) System	06 Apr 2021 17:43:02

US3412243

Folder: SAE USA-US061-2021-MRNA-1273-P301000012

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:34:16

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 18:07:16
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
User entered 'I'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:43:02

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:54:52
User entered 'USA-US061-2021-MRNA-1273-P301000012'	System	05 Mar 2021 16:54:38

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:54:52
User entered 'Yes (Y)'	System	05 Mar 2021 16:54:38

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:54:52
User entered 'No (N)'	System	05 Mar 2021 16:54:38

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:54:52
User entered 'No (N)'	System	05 Mar 2021 16:54:38

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:54:52
User entered 'Yes (Y)'	System	05 Mar 2021 16:54:38

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:54:52
User entered 'No (N)'	System	05 Mar 2021 16:54:38



**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:54:52
User entered 'No (N)'	System	05 Mar 2021 16:54:38

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 16:54:52
User entered 'No (N)'	System	05 Mar 2021 16:54:38

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:42:49
Un-reviewed for Safety.	System	26 Mar 2021 13:37:57
User entered 'Richard'	System	26 Mar 2021 13:37:57
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:54:52
User entered 'Gregory'	System	05 Mar 2021 16:54:38

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:42:49
Un-reviewed for Safety.	System	26 Mar 2021 13:37:57
User entered 'Powell'	System	26 Mar 2021 13:37:57
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:54:52
User entered 'Gottschlich'	System	05 Mar 2021 16:54:38

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:42:49
Un-reviewed for Safety.	System	26 Mar 2021 13:37:57
User entered empty.	System	26 Mar 2021 13:37:57
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:54:52
User entered '4260 Glendale Milford Road'	System	05 Mar 2021 16:54:38

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:42:49
Un-reviewed for Safety.	System	26 Mar 2021 13:37:57
User entered empty.	System	26 Mar 2021 13:37:57
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:54:52
User entered 'Cincinnati'	System	05 Mar 2021 16:54:38

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:42:49
User entered 'OH'	System	26 Mar 2021 13:37:57

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:42:49
Un-reviewed for Safety.	System	26 Mar 2021 13:37:57
User entered empty.	System	26 Mar 2021 13:37:57
Reviewed for Safety.	(b) (4), (b) (6)	05 Mar 2021 16:54:52
User entered '45242'	System	05 Mar 2021 16:54:38



**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:45:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:51:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 13:37:48
User entered 'US'	System	05 Mar 2021 16:55:01

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:34:16**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	22 Apr 2021 18:07:30
User entered '3'	System	06 Apr 2021 17:43:02
User entered '2'	System	26 Mar 2021 13:37:57
User entered '1'	System	05 Mar 2021 16:55:01

**US3412243**

**Folder: SAE USA-US061-2021-MRNA-1273-P301000012**

**Form: Safety Report Form (4)**

**Generated On: 09 Jun 2021 17:34:16**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:42:21
User entered '22/Apr/2021 14:07'	(b) (4) System	22 Apr 2021 18:07:30

US3412243

Folder: SAE USA-US061-2021-MRNA-1273-P301000012

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:34:16

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:42:21
User entered 'I'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:07:30