

US3732249 (Prod: eStudySite - La Mesa - PPDS)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:34:18

All time stamps listed in this document are displayed in GMT

US3732249

Form: Participant Creation

Data signed: (b) (4) 25 Feb 2021 02:01:06

Generated On: 10 Jun 2021 09:34:18

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[Participant ID](#)

US3732249

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

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US3732249

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 25 Feb 2021 02:01:07

Generated On: 10 Jun 2021 09:34:18

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 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	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 25 Feb 2021 02:01:07

Generated On: 10 Jun 2021 09:34:18

Date of Birth (MMM yyyy)	(b) (6) 1939
Age	80
Age Units	YEARS
Age (Derived)	80
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 25 Feb 2021 02:01:07

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Date of Informed Consent (*dd MMM yyyy*) 01 SEP 2020

Month and Year of Informed Consent (derived) SEP 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1	<input type="radio"/>
Amendment 2	<input type="radio"/>
Amendment 3	<input checked="" type="radio"/>
Amendment 4	<input type="radio"/>
Amendment 5	<input type="radio"/>

Was participant enrolled in the study?

Yes	<input checked="" type="radio"/>
No	<input type="radio"/>

If No, indicate reason for screen fail

Withdrew Consent	<input type="radio"/>
Inclusion/Exclusion	<input type="radio"/>
Cohort Full	<input type="radio"/>
Other	<input type="radio"/>

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

Was this participant screened previously?

Yes	<input type="radio"/>
No	<input checked="" type="radio"/>

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

Enrollment Trigger 1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 25 Feb 2021 02:01:07

Generated On: 10 Jun 2021 09:34:18

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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) 25 Feb 2021 02:01:07

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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) 25 Feb 2021 02:01:07

Generated On: 10 Jun 2021 09:34:18

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



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 25 Feb 2021 02:01:07

Generated On: 10 Jun 2021 09:34:18

Condition	PULMONARY EMBOLISM
Start date (dd MMM yyyy)	UN JAN 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN JAN 2008
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	JAN 2008
Stop Year (derived)	2008

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 25 Feb 2021 02:01:07

Generated On: 10 Jun 2021 09:34:18

Condition	BILATERAL EYES CATARACTS
Start date (dd MMM yyyy)	UN UNK 2007
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2008
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2007
Start Year (derived)	2007
Stop Month and Year (derived)	JAN 2008
Stop Year (derived)	2008

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 25 Feb 2021 02:01:07

Generated On: 10 Jun 2021 09:34:18

Condition	BILATERAL EYES CATARACT LENS SURGERY
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2008
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	JAN 2008
Stop Year (derived)	2008

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 25 Feb 2021 02:01:07

Generated On: 10 Jun 2021 09:34:18

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

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 25 Feb 2021 02:01:07

Generated On: 10 Jun 2021 09:34:18

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 25 Feb 2021 02:01:07

Generated On: 10 Jun 2021 09:34:18

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 25 Feb 2021 02:01:07

Generated On: 10 Jun 2021 09:34:18

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

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 25 Feb 2021 02:01:07

Generated On: 10 Jun 2021 09:34:18

Condition	BASAL CELL CARCINOMA - BACK OF THE NECK
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018



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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 25 Feb 2021 02:01:07

Generated On: 10 Jun 2021 09:34:18

Condition	MOH'S SURGERY - NECK
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 25 Feb 2021 02:01:07

Generated On: 10 Jun 2021 09:34:18

Condition	PROSTATE CANCER
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2008
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	JAN 2008
Stop Year (derived)	2008

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 25 Feb 2021 02:01:07

Generated On: 10 Jun 2021 09:34:18

Condition	PROSTECTOMY
Start date (dd MMM yyyy)	UN JAN 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN JAN 2008
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	JAN 2008
Stop Year (derived)	2008

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 25 Feb 2021 02:01:07

Generated On: 10 Jun 2021 09:34:18

Condition	TOBACCO USE
Start date (dd MMM yyyy)	UN UNK 1959
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1966
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1959
Start Year (derived)	1959
Stop Month and Year (derived)	JAN 1966
Stop Year (derived)	1966

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 25 Feb 2021 02:01:07

Generated On: 10 Jun 2021 09:34:18

Condition	ALCOHOL USE
Start date (dd MMM yyyy)	UN UNK 1965
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 1965
Start Year (derived)	1965
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 25 Feb 2021 02:01:07

Generated On: 10 Jun 2021 09:34:18

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	01 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	14:02 (24 HR)
Vital Signs Date and Time (derived)	01 SEP 2020 14:02
Height ( <i>xxx.x</i> )	71.0 in
Weight ( <i>xxx.x</i> )	176.6 lb
BMI ( <i>xxx.x</i> )	24.68220 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) 25 Feb 2021 02:01:07

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 SEP 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 25 Feb 2021 02:01:07

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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** GREATER THAN OR EQUAL TO 65 YEARS OLD

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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) 25 Feb 2021 02:01:07

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 25 Feb 2021 02:01:07

Generated On: 10 Jun 2021 09:34:18

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 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	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 25 Feb 2021 02:01:07

Generated On: 10 Jun 2021 09:34:18

What was the date of randomization? (dd MMM yyyy) 01 SEP 2020

What was the participant's randomization number? 189309

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) 25 Feb 2021 02:01:07

Generated On: 10 Jun 2021 09:34:18

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) 25 Feb 2021 02:01:07

Generated On: 10 Jun 2021 09:34:18

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)	01 SEP 2020
Time of assessment (00:00-23:59)	14:02 (24 HR)
Vital Signs Date and Time (derived)	01 SEP 2020 14:02
Temperature (xxx.x)	97.7 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)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	159 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3732249

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 25 Feb 2021 02:01:07

Generated On: 10 Jun 2021 09:34:18

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)	01 SEP 2020
Time of assessment (00:00-23:59)	15:08 (24 HR)
Vital Signs Date and Time (derived)	01 SEP 2020 15:08
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 25 Feb 2021 02:01:07

Generated On: 10 Jun 2021 09:34:18

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) 25 Feb 2021 02:01:07

Generated On: 10 Jun 2021 09:34:18

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) 01 SEP 2020

What was the treatment time? (00:00-23:59) 14:38 (24 HR)

Treatment Date and Time (derived) 01 SEP 2020 14:38

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) 25 Feb 2021 02:01:07

Generated On: 10 Jun 2021 09:34:18

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	01 SEP 2020
Collection time (00:00-23:59)	14:12 (24 HR)
Collection date and time (derived)	01 SEP 2020 14:12

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 25 Feb 2021 02:01:07

Generated On: 10 Jun 2021 09:34:18

Collection date (dd MMM yyyy)			01 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:07	01 SEP 2020 14:07
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 02:01:07

Generated On: 10 Jun 2021 09:34:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:34:18

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 SEP 2020 15:13

PC Open Date & Time

01 SEP 2020 14:58

PC Close Date & Time

01 SEP 2020 17:28

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:34:18

**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 97.7 °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	01 SEP 2020 18:34
PC Open Date & Time	01 SEP 2020 18:23
PC Close Date & Time	02 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:34:18

**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

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 12:08

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3732249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:34:18

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.5 °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

03 SEP 2020 12:17

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3732249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:34:18

**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

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 12:24

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59



US3732249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:34:18

**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

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

05 SEP 2020 12:52

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3732249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:34:18

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

06 SEP 2020 12:44

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3732249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:34:18

**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

96.5 °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

07 SEP 2020 12:02

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3732249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:34:18

**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

01 SEP 2020 15:14

PC Open Date & Time

01 SEP 2020 14:58

PC Close Date & Time

01 SEP 2020 17:28

US3732249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:34:18

**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

01 SEP 2020 18:35

PC Open Date & Time

01 SEP 2020 18:23

PC Close Date & Time

02 SEP 2020 11:59

US3732249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:34:18

**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

02 SEP 2020 12:09

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3732249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:34:18

**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

03 SEP 2020 12:17

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3732249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:34:18

**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

04 SEP 2020 12:25

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59



US3732249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:34:18

**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

05 SEP 2020 12:53

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3732249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:34:18

**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

06 SEP 2020 12:45

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3732249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:34:18

**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

07 SEP 2020 12:03

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:34:18

**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 ☐

US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:34:18

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

No ☒

Yes ☐

PC Time stamp	01 SEP 2020 15:15
PC Open Date & Time	01 SEP 2020 14:58
PC Close Date & Time	01 SEP 2020 17:28

US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:34:18

**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 ☐

US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:34:18

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

No ☒

Yes ☐

PC Time stamp	01 SEP 2020 18:36
PC Open Date & Time	01 SEP 2020 18:23
PC Close Date & Time	02 SEP 2020 11:59

US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:34:18

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 ☒



US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:34:18

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 12:10
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:34:18

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 ☒

US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:34:18

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 12:18
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:34:18

**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 ☒

US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:34:18

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 12:25
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:34:18

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  
EAB) (1725)

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US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:34:18

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 12:54
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:34:18

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:34:18

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 12:45
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:34:18

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

65 of 2445

US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:34:18

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 12:04
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3732249

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 02:01:07

Generated On: 10 Jun 2021 09:34:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3732249

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 02:01:07

Generated On: 10 Jun 2021 09:34:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732249

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 02:01:07

Generated On: 10 Jun 2021 09:34:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3732249

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 02:01:07

Generated On: 10 Jun 2021 09:34:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732249

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 02:01:07

Generated On: 10 Jun 2021 09:34:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3732249

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 02:01:07

Generated On: 10 Jun 2021 09:34:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732249

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 25 Feb 2021 02:01:07

Generated On: 10 Jun 2021 09:34:18

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 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

US3732249

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 25 Feb 2021 02:01:07

Generated On: 10 Jun 2021 09:34:18

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)	29 SEP 2020
Time of assessment (00:00-23:59)	10:30 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 10:30
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3732249

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 25 Feb 2021 02:01:07

Generated On: 10 Jun 2021 09:34:18

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	29 SEP 2020
Time of assessment (00:00-23:59)	11:40 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 11:40
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	55 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	141 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3732249

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Feb 2021 02:01:07

Generated On: 10 Jun 2021 09:34:18

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 SEP 2020

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

US3732249

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 25 Feb 2021 02:01:07

Generated On: 10 Jun 2021 09:34:18

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) 29 SEP 2020

What was the treatment time? (00:00-23:59) 11:10 (24 HR)

Treatment Date and Time (derived) 29 SEP 2020 11:10

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

US3732249

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Feb 2021 02:01:07

Generated On: 10 Jun 2021 09:34:18

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	29 SEP 2020
Collection time (00:00-23:59)	10:45 (24 HR)
Collection date and time (derived)	29 SEP 2020 10:45

US3732249

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 25 Feb 2021 02:01:07

Generated On: 10 Jun 2021 09:34:18

Collection date (dd MMM yyyy)			29 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:39	29 SEP 2020 10:39
Nasopharyngeal Swab 2	No		



US3732249

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 02:01:07

Generated On: 10 Jun 2021 09:34:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:34:18

**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

29 SEP 2020 12:29

PC Open Date & Time

29 SEP 2020 11:30

PC Close Date & Time

29 SEP 2020 14:00

US3732249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:34:18

**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 97.1 °F

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

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

PC Time Stamp	29 SEP 2020 16:48
PC Open Date & Time	29 SEP 2020 14:55
PC Close Date & Time	30 SEP 2020 11:59

US3732249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:34:18

**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

97.4 °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

30 SEP 2020 14:45

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3732249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:34:18

**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

01 OCT 2020 13:24

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3732249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:34:18

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**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 OCT 2020 14:11

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3732249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:34:18

**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

97.3 °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

03 OCT 2020 15:50

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3732249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:34:18

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

04 OCT 2020 13:08

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59



US3732249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:34:18

**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

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

05 OCT 2020 15:57

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3732249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:34:18

**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

29 SEP 2020 12:29

PC Open Date & Time

29 SEP 2020 11:30

PC Close Date & Time

29 SEP 2020 14:00

US3732249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:34:18

**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

29 SEP 2020 16:49

PC Open Date & Time

29 SEP 2020 14:55

PC Close Date & Time

30 SEP 2020 11:59

US3732249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:34:18

**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

30 SEP 2020 14:45

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3732249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:34:18

**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

01 OCT 2020 13:25

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3732249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:34:18

**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

02 OCT 2020 14:12

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3732249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:34:18

**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

03 OCT 2020 15:50

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3732249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:34:18

**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

04 OCT 2020 13:08

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59



US3732249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:34:18

**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

05 OCT 2020 15:57

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3732249

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:34:18

**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 ☐

US3732249

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:34:18

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

No ☒

Yes ☐

PC Time stamp	29 SEP 2020 12:30
PC Open Date & Time	29 SEP 2020 11:30
PC Close Date & Time	29 SEP 2020 14:00

US3732249

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:34:18

**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 ☐

US3732249

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:34:18

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

No ☒

Yes ☐

PC Time stamp	29 SEP 2020 16:49
PC Open Date & Time	29 SEP 2020 14:55
PC Close Date & Time	30 SEP 2020 11:59

US3732249

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:34:18

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:34:18

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 14:46
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3732249

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:34:18

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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Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:34:18

Yes <input type="checkbox"/>	
PC Time stamp	01 OCT 2020 13:27
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3732249

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:34:18

**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 ☒

US3732249

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:34:18

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 14:12
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3732249

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:34:18

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 ☒

US3732249

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:34:18

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 15:51
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3732249

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:34:18

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 ☒

US3732249

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:34:18

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 13:09
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3732249

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:34:18

**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 ☒



US3732249

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:34:18

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 15:58
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3732249

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 02:01:07

Generated On: 10 Jun 2021 09:34:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

06 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3732249

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 02:01:07

Generated On: 10 Jun 2021 09:34:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732249

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 02:01:07

Generated On: 10 Jun 2021 09:34:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3732249

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 02:01:07

Generated On: 10 Jun 2021 09:34:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732249

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 02:01:07

Generated On: 10 Jun 2021 09:34:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3732249

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 02:01:07

Generated On: 10 Jun 2021 09:34:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732249

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 25 Feb 2021 02:01:07

Generated On: 10 Jun 2021 09:34:18

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 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



US3732249

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 25 Feb 2021 02:01:07

Generated On: 10 Jun 2021 09:34:18

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	30 OCT 2020
Time of assessment (00:00-23:59)	13:15 (24 HR)
Vital Signs Date and Time (derived)	30 OCT 2020 13:15
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3732249

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Feb 2021 02:01:07

Generated On: 10 Jun 2021 09:34:18

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.*

US3732249

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Feb 2021 02:01:07

Generated On: 10 Jun 2021 09:34:18

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	30 OCT 2020
Collection time (00:00-23:59)	13:27 (24 HR)
Collection date and time (derived)	30 OCT 2020 13:27

US3732249

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 02:01:07

Generated On: 10 Jun 2021 09:34:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732249

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

<b>TIMEPOINT</b>	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 NOV 2020 19:55:13
Patient Cloud Open Date & Time	01 NOV 2020 00:01
Patient Cloud Close Date & Time	05 NOV 2020 23:59

US3732249

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

**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

10 NOV 2020 16:34:52

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3732249

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

**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

17 NOV 2020 12:01:44

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 NOV 2020 06:05:42
Patient Cloud Open Date & Time	19 NOV 2020 00:01
Patient Cloud Close Date & Time	23 NOV 2020 23:59



US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

**TIMEPOINT**

DAY 89

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 NOV 2020 12:20:06

Patient Cloud Open Date & Time

26 NOV 2020 00:01

Patient Cloud Close Date & Time

30 NOV 2020 23:59

US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

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	03 DEC 2020 10:06:11
Patient Cloud Open Date & Time	03 DEC 2020 00:01
Patient Cloud Close Date & Time	07 DEC 2020 23:59

US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

**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

10 DEC 2020 11:14:54

Patient Cloud Open Date & Time

10 DEC 2020 00:01

Patient Cloud Close Date & Time

14 DEC 2020 23:59

US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

**TIMEPOINT**

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 DEC 2020 11:00:39

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

**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

24 DEC 2020 15:29:11

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

**TIMEPOINT**

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 DEC 2020 05:54:47

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

**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

07 JAN 2021 14:09:13

Patient Cloud Open Date & Time

07 JAN 2021 00:01

Patient Cloud Close Date & Time

11 JAN 2021 23:59

US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

**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

14 JAN 2021 05:54:14

Patient Cloud Open Date & Time

14 JAN 2021 00:01

Patient Cloud Close Date & Time

18 JAN 2021 23:59



US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

**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

21 JAN 2021 14:53:06

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	29 JAN 2021 18:09:47
Patient Cloud Open Date & Time	28 JAN 2021 00:01
Patient Cloud Close Date & Time	01 FEB 2021 23:59

US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

**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

04 FEB 2021 06:57:58

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59

US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

**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

11 FEB 2021 05:37:32

Patient Cloud Open Date & Time

11 FEB 2021 00:01

Patient Cloud Close Date & Time

15 FEB 2021 23:59

US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

**TIMEPOINT**

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 FEB 2021 05:50:04

Patient Cloud Open Date & Time

18 FEB 2021 00:01

Patient Cloud Close Date & Time

22 FEB 2021 23:59

US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

**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

25 FEB 2021 05:37:59

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

**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

04 MAR 2021 05:42:26

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 MAR 2021 05:47:29
Patient Cloud Open Date & Time	11 MAR 2021 00:01
Patient Cloud Close Date & Time	15 MAR 2021 23:59



US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

**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

20 MAR 2021 16:58:13

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

**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

25 MAR 2021 05:34:23

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

**TIMEPOINT**

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 APR 2021 09:56:27

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

**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

09 APR 2021 15:17:37

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

**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

15 APR 2021 12:22:19

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

**TIMEPOINT**

DAY 236

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 APR 2021 05:38:34

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

**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

29 APR 2021 06:01:46

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

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



**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

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[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

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US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

**TIMEPOINT**

DAY 257

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

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

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

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

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

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

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

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[Patient Cloud Close Date & Time](#)

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17 MAY 2021 23:59

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US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

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

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

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[Patient Cloud Open Date & Time](#)

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20 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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24 MAY 2021 23:59

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US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

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"/>

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

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[Patient Cloud Open Date & Time](#)

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27 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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31 MAY 2021 23:59

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US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

**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 ☐



**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

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[Patient Cloud Close Date & Time](#)

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07 JUN 2021 23:59

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US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

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

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

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[Patient Cloud Open Date & Time](#)

10 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

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US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

**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 ☐

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

**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 ☐

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

**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 ☐



**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

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[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

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US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

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"/>

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

**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 ☐

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

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[Patient Cloud Open Date & Time](#)

22 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

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US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

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"/>



**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

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"/>

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

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[Patient Cloud Close Date & Time](#)

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09 AUG 2021 23:59

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US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

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

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	12 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	16 AUG 2021 23:59
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US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

**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 ☐

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

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[Patient Cloud Close Date & Time](#)

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23 AUG 2021 23:59

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US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

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

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



**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	26 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	30 AUG 2021 23:59
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US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

**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 ☐

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

**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 ☐

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

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[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

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US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

**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 ☐

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

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



**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

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[Patient Cloud Close Date & Time](#)

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27 SEP 2021 23:59

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US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

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"/>

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

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

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

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



**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

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[Patient Cloud Close Date & Time](#)

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25 OCT 2021 23:59

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US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

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

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

**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 ☐

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

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[Patient Cloud Open Date & Time](#)

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04 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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08 NOV 2021 23:59

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US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

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

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

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[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

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US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

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



**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

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[Patient Cloud Open Date & Time](#)

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18 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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22 NOV 2021 23:59

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US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

**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 ☐

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

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[Patient Cloud Open Date & Time](#)

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25 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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29 NOV 2021 23:59

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US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

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"/>

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

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[Patient Cloud Open Date & Time](#)

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02 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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06 DEC 2021 23:59

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US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

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

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	09 DEC 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	13 DEC 2021 23:59
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US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

**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 ☐



**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

**TIMEPOINT**

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	23 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 DEC 2021 23:59

US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

**TIMEPOINT**

DAY 488

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

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

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

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

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

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

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

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[Patient Cloud Close Date & Time](#)

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03 JAN 2022 23:59

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US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

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

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

**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 ☐



**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

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[Patient Cloud Open Date & Time](#)

13 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

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US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

**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 ☐

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

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[Patient Cloud Open Date & Time](#)

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20 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 JAN 2022 23:59

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US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

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

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

**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 ☐

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

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[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

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US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

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



**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

**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 ☐

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

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[Patient Cloud Close Date & Time](#)

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21 FEB 2022 23:59

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US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

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

**US3732249**

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

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**Generated On: 10 Jun 2021 09:34:18**

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

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[Patient Cloud Close Date & Time](#)

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28 FEB 2022 23:59

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US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

**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 ☐

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

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[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

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US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

**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 ☐



**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

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[Patient Cloud Open Date & Time](#)

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10 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 MAR 2022 23:59

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US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

**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 ☐

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

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[Patient Cloud Close Date & Time](#)

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21 MAR 2022 23:59

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US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

**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 ☐

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

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[Patient Cloud Close Date & Time](#)

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28 MAR 2022 23:59

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US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

**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 ☐

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

**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 ☐



**US3732249**

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

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

**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 ☐

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

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="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"/>

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

TIMEPOINT

DAY 607

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

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[Patient Cloud Close Date & Time](#)

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02 MAY 2022 23:59

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US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

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"/>



**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

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[Patient Cloud Close Date & Time](#)

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09 MAY 2022 23:59

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US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

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"/>

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

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[Patient Cloud Open Date & Time](#)

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12 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 MAY 2022 23:59

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US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

**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 ☐

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

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[Patient Cloud Open Date & Time](#)

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19 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 MAY 2022 23:59

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US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

**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 ☐

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

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[Patient Cloud Open Date & Time](#)

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26 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 MAY 2022 23:59

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US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

**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 ☐

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

**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 ☐

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

**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 ☐

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

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[Patient Cloud Open Date & Time](#)

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23 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 JUN 2022 23:59

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US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

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



**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

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[Patient Cloud Close Date & Time](#)

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04 JUL 2022 23:59

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US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

**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 ☐

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

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[Patient Cloud Close Date & Time](#)

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18 JUL 2022 23:59

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US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

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="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"/>

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

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[Patient Cloud Close Date & Time](#)

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25 JUL 2022 23:59

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US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

**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 ☐



**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

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[Patient Cloud Open Date & Time](#)

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04 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 AUG 2022 23:59

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US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

**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 ☐

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

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[Patient Cloud Open Date & Time](#)

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18 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 AUG 2022 23:59

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US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

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



**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	25 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 AUG 2022 23:59
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US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

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

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

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[Patient Cloud Close Date & Time](#)

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05 SEP 2022 23:59

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US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

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"/>

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 SEP 2022 23:59

US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

**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 ☐



**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

**TIMEPOINT**

DAY 761

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

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[Patient Cloud Close Date & Time](#)

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03 OCT 2022 23:59

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US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

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

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

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[Patient Cloud Close Date & Time](#)

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10 OCT 2022 23:59

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US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

**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 ☐

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2022 23:59

US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

**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 ☐



**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	20 OCT 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	24 OCT 2022 23:59
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US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

**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 ☐

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

[Patient Cloud Close Date & Time](#)

31 OCT 2022 23:59

US3732249

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

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"/>

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

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[Patient Cloud Close Date & Time](#)

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07 NOV 2022 23:59

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**US3732249**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary**

**Generated On: 10 Jun 2021 09:34:18**

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		04 MAR 2021 05:40:28

US3732249

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 02:01:07

Generated On: 10 Jun 2021 09:34:18

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3732249

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 02:01:07

Generated On: 10 Jun 2021 09:34:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3732249

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 02:01:07

Generated On: 10 Jun 2021 09:34:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3732249

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 02:01:07

Generated On: 10 Jun 2021 09:34:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732249

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 02:01:07

Generated On: 10 Jun 2021 09:34:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3732249

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 02:01:07

Generated On: 10 Jun 2021 09:34:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732249

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 21:24:26

Generated On: 10 Jun 2021 09:34:18

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3732249

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 21:24:26

Generated On: 10 Jun 2021 09:34:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732249

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 21:24:26

Generated On: 10 Jun 2021 09:34:18

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3732249

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 21:24:26

Generated On: 10 Jun 2021 09:34:18

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 MAR 2021
Time of assessment (00:00-23:59)	09:33 (24 HR)
Vital Signs Date and Time (derived)	25 MAR 2021 09:33
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3732249

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 21:24:26

Generated On: 10 Jun 2021 09:34:18

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 MAR 2021

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

US3732249

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Apr 2021 21:24:26

Generated On: 10 Jun 2021 09:34:18

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	25 MAR 2021
Collection time (00:00-23:59)	09:38 (24 HR)
Collection date and time (derived)	25 MAR 2021 09:38

US3732249

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 21:24:26

Generated On: 10 Jun 2021 09:34:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732249

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 22:22:42

Generated On: 10 Jun 2021 09:34:18

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 27 APR 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3732249

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 22:22:42

Generated On: 10 Jun 2021 09:34:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3732249**

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

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:34:18**

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*

**US3732249**

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

**Form: Continuing**

**Generated On: 10 Jun 2021 09:34:18**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3732249

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID-19 Contact

Data signed: (b) (4) 28 Apr 2021 22:22:42

Generated On: 10 Jun 2021 09:34:18

Date of Contact	26 OCT 2020
Time of Contact	11:30
Date and Time of Contact (derived)	26 OCT 2020 11:30
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>



US3732249

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 25 Feb 2021 02:01:06

Generated On: 10 Jun 2021 09:34:18

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input checked="" type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3732249

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 25 Feb 2021 02:01:06

Generated On: 10 Jun 2021 09:34:18

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	26 OCT 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.0 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
PRODUCTION RELEASE (v12.003		329 of 2445
EAB) (1725)		

US3732249

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 25 Feb 2021 02:01:06

Generated On: 10 Jun 2021 09:34:18

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3732249

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 25 Feb 2021 02:01:06

Generated On: 10 Jun 2021 09:34:18

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3732249

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 25 Feb 2021 02:01:06

Generated On: 10 Jun 2021 09:34:18

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input checked="" type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3732249

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 25 Feb 2021 02:01:06

Generated On: 10 Jun 2021 09:34:18

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	27 OCT 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	96.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 25 Feb 2021 02:01:06

Generated On: 10 Jun 2021 09:34:18

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3732249

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 25 Feb 2021 02:01:06

Generated On: 10 Jun 2021 09:34:18

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>



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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 25 Feb 2021 02:01:06

Generated On: 10 Jun 2021 09:34:18

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input checked="" type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 25 Feb 2021 02:01:06

Generated On: 10 Jun 2021 09:34:18

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	28 OCT 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	96.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 25 Feb 2021 02:01:06

Generated On: 10 Jun 2021 09:34:18

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 25 Feb 2021 02:01:06

Generated On: 10 Jun 2021 09:34:18

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 25 Feb 2021 02:01:06

Generated On: 10 Jun 2021 09:34:18

Symptom Day

Day 1	<input checked="" type="radio"/>
Day 2	<input type="radio"/>
Day 3	<input type="radio"/>
Day 4	<input type="radio"/>
Day 5	<input type="radio"/>
Day 6	<input type="radio"/>
Day 7	<input type="radio"/>
Day 8	<input type="radio"/>
Day 9	<input type="radio"/>
Day 10	<input type="radio"/>
Day 11	<input type="radio"/>
Day 12	<input type="radio"/>
Day 13	<input type="radio"/>
Day 14	<input type="radio"/>
Day 15	<input type="radio"/>
Day 16	<input type="radio"/>
Day 17	<input type="radio"/>
Day 18	<input type="radio"/>
Day 19	<input type="radio"/>
Day 20	<input type="radio"/>
Day 21	<input type="radio"/>
Day 22	<input type="radio"/>
Day 23	<input type="radio"/>
Day 24	<input type="radio"/>
Day 25	<input type="radio"/>
Day 26	<input type="radio"/>
Day 27	<input type="radio"/>
Day 28	<input type="radio"/>
Day 29	<input type="radio"/>
Day 30	<input type="radio"/>
Day 31	<input type="radio"/>
Day 32	<input type="radio"/>

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 25 Feb 2021 02:01:06

Generated On: 10 Jun 2021 09:34:18

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	22 OCT 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	ND - Not Done
---------------	---------------

O2 Saturation Units	%
---------------------	---

Temperature	ND - Not Done
-------------	---------------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 25 Feb 2021 02:01:06

Generated On: 10 Jun 2021 09:34:18

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3732249

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 25 Feb 2021 02:01:06

Generated On: 10 Jun 2021 09:34:18

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>



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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 25 Feb 2021 02:01:06

Generated On: 10 Jun 2021 09:34:18

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input checked="" type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 25 Feb 2021 02:01:06

Generated On: 10 Jun 2021 09:34:18

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	23 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3732249

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 25 Feb 2021 02:01:06

Generated On: 10 Jun 2021 09:34:18

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3732249

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 25 Feb 2021 02:01:06

Generated On: 10 Jun 2021 09:34:18

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 25 Feb 2021 02:01:06

Generated On: 10 Jun 2021 09:34:18

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input checked="" type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 25 Feb 2021 02:01:06

Generated On: 10 Jun 2021 09:34:18

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	24 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 25 Feb 2021 02:01:06

Generated On: 10 Jun 2021 09:34:18

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3732249

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 25 Feb 2021 02:01:06

Generated On: 10 Jun 2021 09:34:18

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>



US3732249

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 25 Feb 2021 02:01:06

Generated On: 10 Jun 2021 09:34:18

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input checked="" type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3732249

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 25 Feb 2021 02:01:06

Generated On: 10 Jun 2021 09:34:18

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	25 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3732249

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 25 Feb 2021 02:01:06

Generated On: 10 Jun 2021 09:34:18

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3732249

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 25 Feb 2021 02:01:06

Generated On: 10 Jun 2021 09:34:18

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3732249

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 25 Feb 2021 02:01:06

Generated On: 10 Jun 2021 09:34:18

Date of Visit	26 OCT 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	26 OCT 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

US3732249

Folder: Covid-19 Assessment 26 Oct 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 25 Feb 2021 02:01:06

Generated On: 10 Jun 2021 09:34:18

---

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

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US3732249

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 25 Feb 2021 02:01:06

Generated On: 10 Jun 2021 09:34:18

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	28 OCT 2020
Day 5	NA (COVID-19 Negative)	
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3732249

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 25 Feb 2021 02:01:06

Generated On: 10 Jun 2021 09:34:18

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 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	SICKD1



US3732249

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 25 Feb 2021 02:01:06

Generated On: 10 Jun 2021 09:34:18

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 OCT 2020
Time of assessment (00:00-23:59)	13:10 (24 HR)
Vital Signs Date and Time (derived)	26 OCT 2020 13:10
Height (xxx.x)	177.0 cm
Weight (xxx.x)	77.5 kg
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3732249

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Feb 2021 02:01:06

Generated On: 10 Jun 2021 09:34:18

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 OCT 2020

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

US3732249

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 25 Feb 2021 02:01:06

Generated On: 10 Jun 2021 09:34:18

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

26 OCT 2020

US3732249

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

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 21:24:26

Generated On: 10 Jun 2021 09:34:18

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

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

Folder OID	UNBLND_DECIDE
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US3732249

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

Form: Unblinding

Data signed: (b) (4) 09 Apr 2021 21:24:26

Generated On: 10 Jun 2021 09:34:18

Date of updated informed consent ( <i>dd MMM yyyy</i> )	25 FEB 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> )	25 FEB 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

US3732249

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 09 Apr 2021 21:24:26

Generated On: 10 Jun 2021 09:34:18

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

US3732249

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 09 Apr 2021 21:24:26

Generated On: 10 Jun 2021 09:34:18

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 FEB 2021
Time of assessment (00:00-23:59)	16:04 (24 HR)
Vital Signs Date and Time (derived)	25 FEB 2021 16:04
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	105 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	52 mmHg
Diastolic Blood Pressure units	MMHG

US3732249

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 09 Apr 2021 21:24:26

Generated On: 10 Jun 2021 09:34:18

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 FEB 2021
Time of assessment (00:00-23:59)	16:59 (24 HR)
Vital Signs Date and Time (derived)	25 FEB 2021 16:59
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG



US3732249

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

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 21:24:26

Generated On: 10 Jun 2021 09:34:18

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 FEB 2021

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

US3732249

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

Form: Exposure

Data signed: (b) (4) 09 Apr 2021 21:24:26

Generated On: 10 Jun 2021 09:34:18

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) 25 FEB 2021

What was the treatment time? (00:00-23:59) 16:26 (24 HR)

Treatment Date and Time (derived) 25 FEB 2021 16:26

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

What was the frequency of the study treatment dosing? ONCE

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

US3732249

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Apr 2021 21:24:26

Generated On: 10 Jun 2021 09:34:18

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

25 FEB 2021

Collection time (00:00-23:59)

15:32 (24 HR)

Collection date and time (derived)

25 FEB 2021 15:32

US3732249

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 09 Apr 2021 21:24:26

Generated On: 10 Jun 2021 09:34:18

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	25 FEB 2021
Collection time (00:00 - 23:59)	15:27
Collection Date and Time (derived)	25 FEB 2021 15:27

US3732249

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

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 21:24:26

Generated On: 10 Jun 2021 09:34:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732249

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 21:24:26

Generated On: 10 Jun 2021 09:34:18

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 04 MAR 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3732249

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 21:24:26

Generated On: 10 Jun 2021 09:34:18

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

US3732249

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 21:24:26

Generated On: 10 Jun 2021 09:34:18

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29



US3732249

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 09 Apr 2021 21:24:26

Generated On: 10 Jun 2021 09:34:18

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)	25 MAR 2021
Time of assessment (00:00-23:59)	09:33 (24 HR)
Vital Signs Date and Time (derived)	25 MAR 2021 09:33
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3732249

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 09 Apr 2021 21:24:26

Generated On: 10 Jun 2021 09:34:18

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	25 MAR 2021
Time of assessment (00:00-23:59)	10:34 (24 HR)
Vital Signs Date and Time (derived)	25 MAR 2021 10:34
Temperature (xxx.x)	98 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	53 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	56 mmHg
Diastolic Blood Pressure units	MMHG

US3732249

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 21:24:26

Generated On: 10 Jun 2021 09:34:18

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 MAR 2021

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

US3732249

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 09 Apr 2021 21:24:26

Generated On: 10 Jun 2021 09:34:18

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) 25 MAR 2021

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

Treatment Date and Time (derived) 25 MAR 2021 09:59

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

US3732249

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 21:24:26

Generated On: 10 Jun 2021 09:34:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732249

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 21:24:26

Generated On: 10 Jun 2021 09:34:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3732249

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 21:24:26

Generated On: 10 Jun 2021 09:34:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732249

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 22:22:42

Generated On: 10 Jun 2021 09:34:18

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 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	OLD57



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Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 22:22:42

Generated On: 10 Jun 2021 09:34:18

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	22 APR 2021
Time of assessment ( <i>00:00-23:59</i> )	10:10 (24 HR)
Vital Signs Date and Time (derived)	22 APR 2021 10:10
Temperature ( <i>xxx.x</i> )	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	59 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	68 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3732249

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 22:22:42

Generated On: 10 Jun 2021 09:34:18

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 APR 2021

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

US3732249

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 22:22:42

Generated On: 10 Jun 2021 09:34:18

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 APR 2021
Collection time (00:00-23:59)	10:13 (24 HR)
Collection date and time (derived)	22 APR 2021 10:13

US3732249

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 25 Feb 2021 02:01:06

Generated On: 10 Jun 2021 09:34:18

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3732249

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 22:22:08

Generated On: 10 Jun 2021 09:34:18

AEID

Adverse event

LOOSE STOOLS

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

22 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

27 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 22:22:08

Generated On: 10 Jun 2021 09:34:18

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3732249

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 22:22:08

Generated On: 10 Jun 2021 09:34:18

AEID	USA-US102-2021-MRNA-1273-P30 1000007
Adverse event	DEEP VEIN THROMBOSIS - RIGHT LEG
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 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	29 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	31 JAN 2021
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 22:22:08

Generated On: 10 Jun 2021 09:34:18

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	



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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 22:22:08

Generated On: 10 Jun 2021 09:34:18

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PATIENT CALLED SITE ON 30JAN2021, STATED HE IS IN HOSPITAL WITH A DEEP VEIN THROMBOSIS IN RIGHT LEG. STARTED 2 WEEKS AGO, EVENTUALLY DIAGNOSED AS DVT. ADMISSION 29JAN2021. ON LOVENOX. NO PROCEDURES. PATIENT STATES NO PHYSICAL EXAM. 09APR2021 MR NARRATIVE UPDATE: 30JAN2021 ECHO SHOWED NORMAL BILATERAL VENTRICLES, NO HEMODYNAMICALLY SIGNIFICANT VALVE DISEASE, AND TRIVIAL POSTERIOR PERICARDIAL EFFUSION. BILATERAL DUPLEX LOWER EXTREMITY ULTRASOUND ON 29JAN2021 SHOWED A NON-OCCLUSIVE DVT IN THE RIGHT COMMON FEMORAL VEIN EXTENDING THROUGH THE THIGH INTO THE POPLITEAL VEIN AND DISTAL CALF VEINS. ROUTINE COVID-19 NASOPHARYNGEAL SWAB TESTED NEGATIVE ON 29JAN2021. FACTOR 5 LEIDEN MUTATION TESTING ON 29JAN2021 WAS NEGATIVE. D-DIMER WAS NOT TESTED PER LAB REPORT.

---

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

---

US3732249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 25 Feb 2021 02:01:06

Generated On: 10 Jun 2021 09:34:18

---

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

Yes ☒

No ☐

---

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

---

US3732249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 22:22:08

Generated On: 10 Jun 2021 09:34:18

Name of Medication WARFARIN

Prophylaxis Yes ☐  
No ☒

Indication PULMONARY EMBOLISM

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 22:22:08

Generated On: 10 Jun 2021 09:34:18

	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 2008	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	29 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 22:22:08

Generated On: 10 Jun 2021 09:34:18

Name of Medication CALCIUM

Prophylaxis Yes ☒  
No ☐

Indication VITAMIN DEFICIENCY

Dose per administration 1600

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 22:22:08

Generated On: 10 Jun 2021 09:34:18

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 22:22:08

Generated On: 10 Jun 2021 09:34:18

Name of Medication VITAMIN D

Prophylaxis Yes ☒  
No ☐

Indication VITAMIN DEFICIENCY

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 22:22:08

Generated On: 10 Jun 2021 09:34:18

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 22:22:08

Generated On: 10 Jun 2021 09:34:18

Name of Medication GAS-X

Prophylaxis Yes ☐  
No ☒

Indication LOOSE STOOLS

Dose per administration 125

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 22:22:08

Generated On: 10 Jun 2021 09:34:18

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	22 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 26 OCT 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 22:22:08

Generated On: 10 Jun 2021 09:34:18

Name of Medication ELIQUIS

Prophylaxis Yes ☐  
No ☒

Indication DVT RIGHT LEG

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 22:22:08

Generated On: 10 Jun 2021 09:34:18

	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)	31 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 22:22:08

Generated On: 10 Jun 2021 09:34:18

Name of Medication LOVENOX

Prophylaxis Yes ☐  
No ☒

Indication DVT RIGHT LEG

Dose per administration 80

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 22:22:08

Generated On: 10 Jun 2021 09:34:18

	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)	29 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		31 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 22:22:08

Generated On: 10 Jun 2021 09:34:18

Name of Medication FAMOTIDINE

Prophylaxis Yes ☒  
No ☐

Indication GI PROPHYLAXIS

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

406 of 2445

US3732249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 22:22:08

Generated On: 10 Jun 2021 09:34:18

	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)	29 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 31 JAN 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>



US3732249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 22:22:08

Generated On: 10 Jun 2021 09:34:18

Name of Medication TETANUS VACCINE

Prophylaxis Yes ☒  
No ☐

Indication TETANUS

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

408 of 2445

US3732249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 22:22:08

Generated On: 10 Jun 2021 09:34:18

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		08 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		08 APR 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3732249

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 09 Apr 2021 21:24:26

Generated On: 10 Jun 2021 09:34:18

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3732249

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 09 Apr 2021 21:24:26

Generated On: 10 Jun 2021 09:34:18

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
30 JAN 2021	ECHOCARDIOGRAM	Diagnostic	
29 JAN 2021	BILATERAL DUPLEX LOWER EXTREMITY ULTRASOUND	Diagnostic	

US3732249

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:34:18

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

US3732249

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:34:18

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 ☐

US3732249

Folder: SAE USA-US102-2021-MRNA-1273-P301000007

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 22:22:42

Generated On: 10 Jun 2021 09:34:18

SAEID	USA-US102-2021-MRNA-1273-P301000007
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	SCOTT
Investigator's Last Name	OVERCASH
Site Address: Street	5565 GROSSMONT CENTER DR
Site Address: City	LA MESA
Site Address: State	CA
Site Address: Postal Code	91942
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3732249

Folder: SAE USA-US102-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 22:22:42

Generated On: 10 Jun 2021 09:34:18

SAEID	USA-US102-2021-MRNA-1273-P301000007
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	SCOTT
Investigator's Last Name	OVERCASH
Site Address: Street	5565 GROSSMONT CENTER DR
Site Address: City	LA MESA
Site Address: State	CA
Site Address: Postal Code	91942
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	01/FEB/2021 13:38
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True



US3732249

Folder: SAE USA-US102-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 22:22:42

Generated On: 10 Jun 2021 09:34:18

SAEID	USA-US102-2021-MRNA-1273-P301000007
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	SCOTT
Investigator's Last Name	OVERCASH
Site Address: Street	5565 GROSSMONT CENTER DR
Site Address: City	LA MESA
Site Address: State	CA
Site Address: Postal Code	91942
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	26/MAR/2021 11:25
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

US3732249

Folder: SAE USA-US102-2021-MRNA-1273-P301000007

Form: Safety Report Form (3)

Data signed: (b) (4) 28 Apr 2021 22:22:42

Generated On: 10 Jun 2021 09:34:18

SAEID	USA-US102-2021-MRNA-1273-P301000007
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	SCOTT
Investigator's Last Name	OVERCASH
Site Address: Street	5565 GROSSMONT CENTER DR
Site Address: City	LA MESA
Site Address: State	CA
Site Address: Postal Code	91942
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	02/APR/2021 10:51
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3732249

Folder: SAE USA-US102-2021-MRNA-1273-P301000007

Form: Safety Report Form (4)

Data signed: (b) (4) 28 Apr 2021 22:22:42

Generated On: 10 Jun 2021 09:34:18

SAEID	USA-US102-2021-MRNA-1273-P301000007
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	SCOTT
Investigator's Last Name	OVERCASH
Site Address: Street	5565 GROSSMONT CENTER DR
Site Address: City	LA MESA
Site Address: State	CA
Site Address: Postal Code	91942
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	12/APR/2021 14:56
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3732249

Folder: SAE USA-US102-2021-MRNA-1273-P301000007

Form: Safety Report Form (5)

Data signed: (b) (4) 28 Apr 2021 22:22:42

Generated On: 10 Jun 2021 09:34:18

SAEID	USA-US102-2021-MRNA-1273-P301000007
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	SCOTT
Investigator's Last Name	OVERCASH
Site Address: Street	5565 GROSSMONT CENTER DR
Site Address: City	LA MESA
Site Address: State	CA
Site Address: Postal Code	91942
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	26/APR/2021 10:11
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

US3732249 (Prod: eStudySite - La Mesa - PPDS)

**US3732249**

**Form: Participant Creation**

**Generated On: 10 Jun 2021 09:34:18**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'US3732249'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	01 Sep 2020 20:59:34

**US3732249**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:34:18**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:20
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	02 Sep 2020 16:34:32

**US3732249**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:20
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '01 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 20:59:35



US3732249

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:34:18

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:20
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Clinic (Clinic)'	Lauren Arnett (b) (4)	02 Sep 2020 16:34:32

**US3732249**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:34:18**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:20
User entered 'SCRN'	System	02 Sep 2020 16:34:32

**US3732249**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:34:18**

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered (b) (6) 1939'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 20:59:36

**US3732249**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:34:18**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '80'	Lauren Arnett (b) (4)	02 Sep 2020 16:35:23

**US3732249**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:34:18**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User entered 'YEARS'	System	02 Sep 2020 16:35:23

**US3732249**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:34:18**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User entered '80'	System	01 Sep 2020 21:41:35

**US3732249**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:34:18**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Male (M)'	(b) (4) Lauren Arnett (b) (4)	02 Sep 2020 16:35:23

**US3732249**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:34:18**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Lauren Arnett (b) (4)	02 Sep 2020 16:35:23



**US3732249**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:34:18**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'I'	Lauren Arnett (b) (4)	02 Sep 2020 16:35:23

**US3732249**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:34:18**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '0'	Lauren Arnett (b) (4)	02 Sep 2020 16:35:23

**US3732249**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:34:18**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '0'	Lauren Arnett (b) (4)	02 Sep 2020 16:35:23

**US3732249**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:34:18**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '0'	Lauren Arnett (b) (4)	02 Sep 2020 16:35:23

**US3732249**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:34:18**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '0'	Lauren Arnett (b) (4)	02 Sep 2020 16:35:23

**US3732249**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:34:18**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '0'	Lauren Arnett (b) (4)	02 Sep 2020 16:35:23

**US3732249**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:34:18**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered empty.	(b) (4) Lauren Arnett (b) (4)	02 Sep 2020 16:35:23

**US3732249**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:34:18**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '0'	Lauren Arnett (b) (4)	02 Sep 2020 16:35:23



**US3732249**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:34:18**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '0'	Lauren Arnett (b) (4)	02 Sep 2020 16:35:23

**US3732249**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:34:18**

**Date of Informed Consent** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '01 Sep 2020'	Lauren Arnett (b) (4)	01 Sep 2020 21:41:35

**US3732249**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User entered 'Sep 2020'	System	01 Sep 2020 21:41:35

**US3732249**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User entered '2020'	System	01 Sep 2020 21:41:35

**US3732249**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:34:18**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Amendment 3 (3)'	Lauren Arnett (b) (4)	01 Sep 2020 21:41:35

**US3732249**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Yes (Y)'	(b) (4) Lauren Arnett (b) (4)	01 Sep 2020 21:41:35

**US3732249**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:34:18**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered empty.	(b) (4) Lauren Arnett (b) (4)	01 Sep 2020 21:41:35

**US3732249**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:34:18**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered empty.	Lauren Arnett (b) (4)	01 Sep 2020 21:41:35



**US3732249**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:34:18**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'No (N)'	Lauren Arnett (b) (4)	01 Sep 2020 21:41:35

**US3732249**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:34:18**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 20:59:35

**US3732249**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:34:18**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User entered 'I'	System	01 Sep 2020 21:41:40

**US3732249**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	01 Sep 2020 21:41:40

**US3732249**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 10 Jun 2021 09:34:18**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	02 Sep 2020 16:37:52

US3732249

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:34:18

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergy to antibiotic - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 16:39:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 16:39:56
Data point term sent to Coder	System	02 Sep 2020 16:38:45
User entered 'allergy to cipro'	Lauren Arnett (b) (4)	02 Sep 2020 16:38:07

**US3732249**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'un UNK 2010'	Lauren Arnett (b) (4)	02 Sep 2020 16:38:07

**US3732249**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '0'	Lauren Arnett (b) (4)	02 Sep 2020 16:38:07



**US3732249**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	02 Sep 2020 16:38:07

**US3732249**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:34:18**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered empty.	Lauren Arnett (b) (4)	02 Sep 2020 16:38:07

**US3732249**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '0'	Lauren Arnett (b) (4)	02 Sep 2020 16:38:07

**US3732249**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User entered 'Jan 2010'	System	02 Sep 2020 16:38:07

**US3732249**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User entered '2010'	System	02 Sep 2020 16:38:07

**US3732249**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User entered empty.	System	02 Sep 2020 16:38:07

**US3732249**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User entered empty.	System	02 Sep 2020 16:38:07

US3732249

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:34:18

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Pulmonary vascular disorders, HLT: Pulmonary thrombotic and embolic conditions, PT: Pulmonary embolism, LLT: Pulmonary embolism - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 16:39:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 16:39:57
Data point term sent to Coder	System	02 Sep 2020 16:38:48
User entered 'pulmonary embolism'	Lauren Arnett (b) (4)	02 Sep 2020 16:38:32



**US3732249**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'un Jan 2008'	Lauren Arnett (b) (4)	02 Sep 2020 16:38:32

**US3732249**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '0'	Lauren Arnett (b) (4)	02 Sep 2020 16:38:32

**US3732249**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'No (N)'	Lauren Arnett (b) (4)	02 Sep 2020 16:38:32

**US3732249**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:34:18**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'un Jan 2008'	Lauren Arnett (b) (4)	02 Sep 2020 16:38:32

**US3732249**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '0'	Lauren Arnett (b) (4)	02 Sep 2020 16:38:32

**US3732249**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User entered 'Jan 2008'	System	02 Sep 2020 16:38:32

**US3732249**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User entered '2008'	System	02 Sep 2020 16:38:32

**US3732249**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User entered 'Jan 2008'	System	02 Sep 2020 16:38:32



**US3732249**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User entered '2008'	System	02 Sep 2020 16:38:32

US3732249

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:34:18

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Bilateral cataracts - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	02 Sep 2020 16:39:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 16:39:57
Data point term sent to Coder	System	02 Sep 2020 16:38:51
User entered 'bilateral eyes cataracts'	Lauren Arnett (b) (4) (b) (4)	02 Sep 2020 16:38:51

**US3732249**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'un UNK 2007'	Lauren Arnett (b) (4)	02 Sep 2020 16:38:51

**US3732249**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:34:18**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '0'	Lauren Arnett (b) (4)	02 Sep 2020 16:38:51

**US3732249**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:34:18**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'No (N)'	Lauren Arnett (b) (4)	02 Sep 2020 16:38:51

**US3732249**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:34:18**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'un UNK 2008'	Lauren Arnett (b) (4)	02 Sep 2020 16:38:51

**US3732249**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:34:18**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '0'	Lauren Arnett (b) (4)	02 Sep 2020 16:38:51

**US3732249**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User entered 'Jan 2007'	System	02 Sep 2020 16:38:51



**US3732249**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User entered '2007'	System	02 Sep 2020 16:38:51

**US3732249**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User entered 'Jan 2008'	System	02 Sep 2020 16:38:51

**US3732249**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User entered '2008'	System	02 Sep 2020 16:38:51

US3732249

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:34:18

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Lens therapeutic procedures, PT: Cataract operation, LLT: Cataract operation - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	24 Oct 2020 23:51:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Oct 2020 23:51:41
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Lens therapeutic procedures, PT: Cataract operation, LLT: Bilateral cataract extraction - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 21:32:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 21:32:47
Data point term sent to Coder	System	02 Sep 2020 16:39:58
User entered 'bilateral eyes cataract lens surgery'	Lauren Arnett (b) (4) (b) (4)	02 Sep 2020 16:39:28

**US3732249**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'un UNK 2008'	Lauren Arnett (b) (4)	02 Sep 2020 16:39:28

**US3732249**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:34:18**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '0'	Lauren Arnett (b) (4)	02 Sep 2020 16:39:28

**US3732249**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:34:18**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'No (N)'	Lauren Arnett (b) (4)	02 Sep 2020 16:39:28

**US3732249**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:34:18**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'un UNK 2008'	Lauren Arnett (b) (4)	02 Sep 2020 16:39:28



**US3732249**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:34:18**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '0'	Lauren Arnett (b) (4)	02 Sep 2020 16:39:28

**US3732249**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User entered 'Jan 2008'	System	02 Sep 2020 16:39:28

**US3732249**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User entered '2008'	System	02 Sep 2020 16:39:28

**US3732249**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User entered 'Jan 2008'	System	02 Sep 2020 16:39:28

**US3732249**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User entered '2008'	System	02 Sep 2020 16:39:28

US3732249

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:34:18

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Herpes zoster, LLT: Shingles - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 16:40:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 16:40:43
Data point term sent to Coder	System	02 Sep 2020 16:39:58
User entered 'shingles'	Lauren Arnett (b) (4)	02 Sep 2020 16:39:44

**US3732249**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'un UNK 2010'	Lauren Arnett (b) (4)	02 Sep 2020 16:39:44

**US3732249**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:34:18**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '0'	Lauren Arnett (b) (4)	02 Sep 2020 16:39:44



**US3732249**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:34:18**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'No (N)'	Lauren Arnett (b) (4)	02 Sep 2020 16:39:44

**US3732249**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:34:18**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'un UNK 2010'	Lauren Arnett (b) (4)	02 Sep 2020 16:39:44

**US3732249**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:34:18**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '0'	Lauren Arnett (b) (4)	02 Sep 2020 16:39:44

**US3732249**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User entered 'Jan 2010'	System	02 Sep 2020 16:39:44

**US3732249**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User entered '2010'	System	02 Sep 2020 16:39:44

**US3732249**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User entered 'Jan 2010'	System	02 Sep 2020 16:39:44

**US3732249**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User entered '2010'	System	02 Sep 2020 16:39:44

US3732249

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:34:18

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Cornification and dystrophic skin disorders, HLT: Skin preneoplastic conditions NEC, PT: Actinic keratosis, LLT: Actinic keratosis - version MedDRA\23.0.	Coder Import (b) (4)	02 Sep 2020 17:09:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	02 Sep 2020 17:09:46
Data point term sent to Coder	System	02 Sep 2020 16:41:01
User entered 'actinic keratosis - face and scalp'	Lauren Arnett (b) (4)	02 Sep 2020 16:40:03



**US3732249**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'un UNK 2010'	Lauren Arnett (b) (4)	02 Sep 2020 16:40:03

**US3732249**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:34:18**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '0'	Lauren Arnett (b) (4)	02 Sep 2020 16:40:03

**US3732249**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:34:18**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	02 Sep 2020 16:40:03

**US3732249**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:34:18**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered empty.	Lauren Arnett (b) (4)	02 Sep 2020 16:40:03

**US3732249**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:34:18**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '0'	Lauren Arnett (b) (4)	02 Sep 2020 16:40:03

**US3732249**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User entered 'Jan 2010'	System	02 Sep 2020 16:40:03

**US3732249**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User entered '2010'	System	02 Sep 2020 16:40:03

**US3732249**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User entered empty.	System	02 Sep 2020 16:40:03



**US3732249**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User entered empty.	System	02 Sep 2020 16:40:03

US3732249

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:34:18

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Miscellaneous and site unspecified neoplasms malignant and unspecified, HLT: Neoplasms malignant site unspecified NEC, PT: Squamous cell carcinoma, LLT: Squamous cell carcinoma - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	07 Sep 2020 15:56:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Sep 2020 15:56:50
Data point term sent to Coder	System	02 Sep 2020 16:41:03
User entered 'squamous cell carcinoma - right ear'	Lauren Arnett (b) (4) (b) (4)	02 Sep 2020 16:40:26

**US3732249**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'un UNK 2016'	Lauren Arnett (b) (4)	02 Sep 2020 16:40:26

**US3732249**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:34:18**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '0'	Lauren Arnett (b) (4)	02 Sep 2020 16:40:26

**US3732249**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:34:18**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'No (N)'	Lauren Arnett (b) (4)	02 Sep 2020 16:40:26

**US3732249**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:34:18**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'un UNK 2016'	Lauren Arnett (b) (4)	02 Sep 2020 16:40:26

**US3732249**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:34:18**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '0'	Lauren Arnett (b) (4)	02 Sep 2020 16:40:26

**US3732249**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User entered 'Jan 2016'	System	02 Sep 2020 16:40:26



**US3732249**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User entered '2016'	System	02 Sep 2020 16:40:26

**US3732249**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User entered 'Jan 2016'	System	02 Sep 2020 16:40:26

**US3732249**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User entered '2016'	System	02 Sep 2020 16:40:26

US3732249

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:34:18

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User coded data point as SOC: Surgical and medical procedures, HLT: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Cancer surgery, LLT: Squamous cell carcinoma excision - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	07 Sep 2020 15:57:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Sep 2020 15:57:51
Data point term sent to Coder	System	02 Sep 2020 16:42:06
User entered 'squamous cell carcinoma removal surgery - right ear'	Lauren Arnett (b) (4) (b) (4)	02 Sep 2020 16:41:11

**US3732249**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'un UNK 2016'	Lauren Arnett (b) (4)	02 Sep 2020 16:41:11

**US3732249**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:34:18**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '0'	Lauren Arnett (b) (4)	02 Sep 2020 16:41:11

**US3732249**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:34:18**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'No (N)'	Lauren Arnett (b) (4)	02 Sep 2020 16:41:11

**US3732249**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:34:18**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'un UNK 2016'	Lauren Arnett (b) (4)	02 Sep 2020 16:41:11



**US3732249**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:34:18**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '0'	Lauren Arnett (b) (4)	02 Sep 2020 16:41:11

**US3732249**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User entered 'Jan 2016'	System	02 Sep 2020 16:41:11

**US3732249**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User entered '2016'	System	02 Sep 2020 16:41:11

**US3732249**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User entered 'Jan 2016'	System	02 Sep 2020 16:41:11

**US3732249**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User entered '2016'	System	02 Sep 2020 16:41:11

US3732249

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:34:18

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Skin neoplasms malignant and unspecified, HLT: Skin neoplasms malignant and unspecified (excl melanoma), PT: Basal cell carcinoma, LLT: Basal cell carcinoma - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	02 Sep 2020 17:23:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	02 Sep 2020 17:23:52
Data point term sent to Coder	System	02 Sep 2020 16:42:07
User entered 'basal cell carcinoma - back of the neck'	Lauren Arnett (b) (4) (b) (4)	02 Sep 2020 16:41:33

**US3732249**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'un UNK 2018'	Lauren Arnett (b) (4)	02 Sep 2020 16:41:33

**US3732249**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:34:18**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '0'	Lauren Arnett (b) (4)	02 Sep 2020 16:41:33



**US3732249**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:34:18**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'No (N)'	Lauren Arnett (b) (4)	02 Sep 2020 16:41:33

**US3732249**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:34:18**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'un UNK 2018'	Lauren Arnett (b) (4)	02 Sep 2020 16:41:33

**US3732249**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:34:18**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '0'	Lauren Arnett (b) (4)	02 Sep 2020 16:41:33

**US3732249**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User entered 'Jan 2018'	System	02 Sep 2020 16:41:33

**US3732249**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User entered '2018'	System	02 Sep 2020 16:41:33

**US3732249**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User entered 'Jan 2018'	System	02 Sep 2020 16:41:33

**US3732249**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User entered '2018'	System	02 Sep 2020 16:41:33

US3732249

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:34:18

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User coded data point as SOC: Surgical and medical procedures, HLGT: Skin and subcutaneous tissue therapeutic procedures, HLT: Skin and subcutaneous tissue therapeutic procedures NEC, PT: Micrographic skin surgery, LLT: Mohs micrographic surgery - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	06 Sep 2020 23:04:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Sep 2020 23:04:42
Data point term sent to Coder	System	02 Sep 2020 16:42:08
User entered 'moh's surgery - neck'	Lauren Arnett (b) (4) (b) (4)	02 Sep 2020 16:41:53



**US3732249**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'un UNK 2018'	Lauren Arnett (b) (4)	02 Sep 2020 16:41:53

**US3732249**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:34:18**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '0'	Lauren Arnett (b) (4)	02 Sep 2020 16:41:53

**US3732249**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:34:18**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'No (N)'	Lauren Arnett (b) (4)	02 Sep 2020 16:41:53

**US3732249**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:34:18**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'un UNK 2018'	Lauren Arnett (b) (4)	02 Sep 2020 16:41:53

**US3732249**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:34:18**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '0'	Lauren Arnett (b) (4)	02 Sep 2020 16:41:53

**US3732249**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User entered 'Jan 2018'	System	02 Sep 2020 16:41:53

**US3732249**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User entered '2018'	System	02 Sep 2020 16:41:53

**US3732249**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User entered 'Jan 2018'	System	02 Sep 2020 16:41:53



**US3732249**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User entered '2018'	System	02 Sep 2020 16:41:53

US3732249

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:34:18

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms male malignant and unspecified, HLT: Prostatic neoplasms malignant, PT: Prostate cancer, LLT: Prostate cancer - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	02 Sep 2020 16:43:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 16:43:44
Data point term sent to Coder	System	02 Sep 2020 16:42:10
User entered 'prostate cancer'	Lauren Arnett (b) (4)	02 Sep 2020 16:42:10
	(b) (4)	

**US3732249**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'un UNK 2008'	Lauren Arnett (b) (4)	02 Sep 2020 16:42:10

**US3732249**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:34:18**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '0'	Lauren Arnett (b) (4)	02 Sep 2020 16:42:10

**US3732249**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:34:18**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'No (N)'	Lauren Arnett (b) (4)	02 Sep 2020 16:42:10

**US3732249**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:34:18**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'un UNK 2008'	Lauren Arnett (b) (4)	02 Sep 2020 16:42:10

**US3732249**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:34:18**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '0'	Lauren Arnett (b) (4)	02 Sep 2020 16:42:10

**US3732249**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User entered 'Jan 2008'	System	02 Sep 2020 16:42:10



**US3732249**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User entered '2008'	System	02 Sep 2020 16:42:10

**US3732249**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User entered 'Jan 2008'	System	02 Sep 2020 16:42:10

**US3732249**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User entered '2008'	System	02 Sep 2020 16:42:10

US3732249

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:34:18

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User coded data point as SOC: Surgical and medical procedures, HLGT: Male genital tract therapeutic procedures, HLT: Prostatic therapeutic procedures, PT: Prostatectomy, LLT: Prostatectomy - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 16:43:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 16:43:47
Data point term sent to Coder	System	02 Sep 2020 16:43:13
User entered 'prostatectomy'	Lauren Arnett (b) (4)	02 Sep 2020 16:42:36

**US3732249**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'un Jan 2008'	Lauren Arnett (b) (4)	02 Sep 2020 16:42:36

**US3732249**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:34:18**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '0'	Lauren Arnett (b) (4)	02 Sep 2020 16:42:36

**US3732249**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:34:18**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'No (N)'	Lauren Arnett (b) (4)	02 Sep 2020 16:42:36

**US3732249**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:34:18**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'un Jan 2008'	Lauren Arnett (b) (4)	02 Sep 2020 16:42:36



**US3732249**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:34:18**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '0'	Lauren Arnett (b) (4)	02 Sep 2020 16:42:36

**US3732249**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User entered 'Jan 2008'	System	02 Sep 2020 16:42:36

**US3732249**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User entered '2008'	System	02 Sep 2020 16:42:36

**US3732249**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User entered 'Jan 2008'	System	02 Sep 2020 16:42:36

**US3732249**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User entered '2008'	System	02 Sep 2020 16:42:36

US3732249

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:34:18

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User coded data point as SOC: Social circumstances, HLT: Tobacco use, PT: Tobacco user, LLT: Tobacco user - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 16:43:48
Data point term sent to Coder	(b) (4)	
User entered 'tobacco use'	System	02 Sep 2020 16:43:13
	Lauren Arnett (b) (4)	02 Sep 2020 16:42:59
	(b) (4)	

**US3732249**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'un UNK 1959'	Lauren Arnett (b) (4)	02 Sep 2020 16:42:59

**US3732249**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:34:18**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '0'	Lauren Arnett (b) (4)	02 Sep 2020 16:42:59



**US3732249**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:34:18**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'No (N)'	Lauren Arnett (b) (4)	02 Sep 2020 16:42:59

**US3732249**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:34:18**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'un UNK 1966'	Lauren Arnett (b) (4)	02 Sep 2020 16:42:59

**US3732249**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:34:18**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '0'	Lauren Arnett (b) (4)	02 Sep 2020 16:42:59

**US3732249**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User entered 'Jan 1959'	System	02 Sep 2020 16:42:59

**US3732249**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User entered '1959'	System	02 Sep 2020 16:42:59

**US3732249**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User entered 'Jan 1966'	System	02 Sep 2020 16:42:59

**US3732249**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User entered '1966'	System	02 Sep 2020 16:42:59

US3732249

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:34:18

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User coded data point as SOC: Social circumstances, HLT: Lifestyle issues, HLT: Alcohol product use, PT: Alcohol use, LLT: Alcohol use - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 16:44:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 16:44:49
Data point term sent to Coder	System	02 Sep 2020 16:43:16
User entered 'alcohol use'	Lauren Arnett (b) (4)	02 Sep 2020 16:43:13



**US3732249**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'un UNK 1965'	Lauren Arnett (b) (4)	02 Sep 2020 16:43:13

**US3732249**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:34:18**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '0'	Lauren Arnett (b) (4)	02 Sep 2020 16:43:13

**US3732249**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:34:18**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	02 Sep 2020 16:43:13

**US3732249**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:34:18**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered empty.	Lauren Arnett (b) (4)	02 Sep 2020 16:43:13

**US3732249**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:34:18**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '0'	Lauren Arnett (b) (4)	02 Sep 2020 16:43:13

**US3732249**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User entered 'Jan 1965'	System	02 Sep 2020 16:43:13

**US3732249**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User entered '1965'	System	02 Sep 2020 16:43:13

**US3732249**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User entered empty.	System	02 Sep 2020 16:43:13



**US3732249**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User entered empty.	System	02 Sep 2020 16:43:13

**US3732249**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:20
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	02 Sep 2020 16:44:01

**US3732249**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:20
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '01 Sep 2020'	(b) (4) Lauren Arnett (b) (4)	02 Sep 2020 16:44:01

**US3732249**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:20
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '14:02'	Lauren Arnett (b) (4)	02 Sep 2020 16:44:01

**US3732249**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:20
User entered '01 Sep 2020 14:02'	System	02 Sep 2020 16:44:01

**US3732249**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:20
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '71.0' in	(b) (4) Lauren Arnett (b) (4)	02 Sep 2020 16:44:01
DataPoint set to visible.	(b) (4) System	01 Sep 2020 21:41:40

**US3732249**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:20
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '176.6' lb	(b) (4) Lauren Arnett (b) (4)	02 Sep 2020 16:44:01
DataPoint set to visible.	(b) (4) System	01 Sep 2020 21:41:40

US3732249

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:34:18

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:20
User entered '24.68220'	System	02 Sep 2020 16:44:01
DataPoint set to visible.	System	01 Sep 2020 21:41:40



**US3732249**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:20
User entered 'kg/m2'	System	02 Sep 2020 16:44:01
DataPoint set to visible.	System	01 Sep 2020 21:41:40

**US3732249**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:20
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered missing code ND - Not Done.	(b) (4) Lauren Arnett (b) (4)	02 Sep 2020 16:44:01

**US3732249**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:20
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered empty.	(b) (4) Lauren Arnett (b) (4)	02 Sep 2020 16:44:01

**US3732249**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:20
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered empty.	Lauren Arnett (b) (4)	02 Sep 2020 16:44:01

**US3732249**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:20
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered missing code ND - Not Done.	Lauren Arnett (b) (4)	02 Sep 2020 16:44:01

**US3732249**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:20
User entered 'bpm'	System	02 Sep 2020 16:44:01

US3732249

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:34:18

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:20
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered missing code ND - Not Done.	(b) (4) Lauren Arnett (b) (4)	02 Sep 2020 16:44:01

**US3732249**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:20
User entered 'breaths/min'	System	02 Sep 2020 16:44:01



**US3732249**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:20
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered missing code ND - Not Done.	(b) (4) Lauren Arnett (b) (4)	02 Sep 2020 16:44:01

**US3732249**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:20
User entered 'mmHg'	System	02 Sep 2020 16:44:01

**US3732249**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:20
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered missing code ND - Not Done.	Lauren Arnett (b) (4)	02 Sep 2020 16:44:01

**US3732249**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:20
User entered 'mmHg'	System	02 Sep 2020 16:44:01

US3732249

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:34:18

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	27 Apr 2021 05:41:20

**US3732249**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	27 Apr 2021 05:41:20

**US3732249**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:34:18**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	02 Sep 2020 16:44:10

**US3732249**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:34:18**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '01 Sep 2020'	Lauren Arnett (b) (4)	02 Sep 2020 16:44:10



US3732249

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:34:18

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'No (N)'	Lauren Arnett (b) (4)	02 Sep 2020 16:45:19

US3732249

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:34:18

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'No (N)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	02 Sep 2020 16:45:19

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:34:18

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'No (N)'	Lauren Arnett (b) (4)	02 Sep 2020 16:45:19

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:34:18

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'No (N)'	Lauren Arnett (b) (4)	02 Sep 2020 16:45:19

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:34:18

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'No (N)'	Lauren Arnett (b) (4)	02 Sep 2020 16:45:19

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Folder: Screening

Form: Risk of Exposure

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[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'No (N)'	Lauren Arnett (b) (4)	02 Sep 2020 16:45:19

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:34:18

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'No (N)'	Lauren Arnett (b) (4)	02 Sep 2020 16:45:19

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:34:18

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'No (N)'	Lauren Arnett (b) (4)	02 Sep 2020 16:45:19



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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:34:18

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	02 Sep 2020 16:45:19

US3732249

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:34:18

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'No (N)'	Lauren Arnett (b) (4)	02 Sep 2020 16:45:19

US3732249

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:34:18

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'No (N)'	Lauren Arnett (b) (4)	02 Sep 2020 16:45:19

**US3732249**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:34:18**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	02 Sep 2020 16:45:19

**US3732249**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:34:18**

**[Specify](#)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'greater than or equal to 65 years old'	Lauren Arnett (b) (4)	02 Sep 2020 16:45:19

**US3732249**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:34:18**

**No Risk Identified**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '0'	Lauren Arnett (b) (4)	02 Sep 2020 16:45:19

US3732249

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:34:18

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '0'	Lauren Arnett (b) (4)	02 Sep 2020 16:45:19

US3732249

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:34:18

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '0'	Lauren Arnett (b) (4)	02 Sep 2020 16:45:19



US3732249

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:34:18

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '0'	(b) (4) Lauren Arnett (b) (4)	02 Sep 2020 16:45:19

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:34:18

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '0'	Lauren Arnett (b) (4)	02 Sep 2020 16:45:19

US3732249

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:34:18

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'I'	Lauren Arnett (b) (4)	02 Sep 2020 16:45:19

**US3732249**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:34:18**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '0'	Lauren Arnett (b) (4)	02 Sep 2020 16:45:19

US3732249

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:34:18

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered empty.	Lauren Arnett (b) (4)	02 Sep 2020 16:45:19

**US3732249**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:34:18**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	02 Sep 2020 16:45:30

**US3732249**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '01 Sep 2020'	Lauren Arnett (b) (4)	02 Sep 2020 16:45:30

**US3732249**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:34:18**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Clinic (Clinic)'	Lauren Arnett (b) (4)	02 Sep 2020 16:45:30



**US3732249**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:34:18**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User entered 'VISIT1'	System	02 Sep 2020 16:45:30

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:34:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '01 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 21:09:27

**US3732249**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:34:18**

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '189309'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 21:09:27

US3732249

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:34:18

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 21:09:27

**US3732249**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:34:18**

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)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'No (N)'	Lauren Arnett (b) (4)	02 Sep 2020 16:46:17

US3732249

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:34:18

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)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'No (N)'	Lauren Arnett (b) (4)	02 Sep 2020 16:46:17

**US3732249**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:34:18**

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'No (N)'	Lauren Arnett (b) (4)	02 Sep 2020 16:46:17

**US3732249**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:34:18**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'No (N)'	Lauren Arnett (b) (4)	02 Sep 2020 16:46:17



**US3732249**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:34:18**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'No (N)'	Lauren Arnett (b) (4)	02 Sep 2020 16:46:17

**US3732249**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:34:18**

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'No (N)'	Lauren Arnett (b) (4)	22 Sep 2020 22:12:51
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 09:02:56
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 09:02:55

US3732249

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:34:18

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User closed query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:20:33
Query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' answered with 'updated' (Site from DM).	Lauren Arnett (b) (4) (b) (4)	22 Sep 2020 22:12:21
User entered missing code ND - Not Done; reason for change Data Entry Error	Lauren Arnett (b) (4) (b) (4)	22 Sep 2020 22:12:15
User opened query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 14:28:41
User entered empty.	Lauren Arnett (b) (4) (b) (4)	02 Sep 2020 16:47:27

**US3732249**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:34:18**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	22 Sep 2020 22:12:15
User entered empty.	Lauren Arnett (b) (4)	02 Sep 2020 16:47:27
	(b) (4)	

US3732249

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:34:18

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User closed query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:20:33
Query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' answered with 'updated' (Site from DM).	Lauren Arnett (b) (4) (b) (4)	22 Sep 2020 22:12:21
User entered missing code ND - Not Done; reason for change Data Entry Error	Lauren Arnett (b) (4) (b) (4)	22 Sep 2020 22:12:15
User opened query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 14:28:41
User entered empty.	Lauren Arnett (b) (4) (b) (4)	02 Sep 2020 16:47:27

US3732249

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:34:18

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	22 Sep 2020 22:12:15
User entered empty.	Lauren Arnett (b) (4)	02 Sep 2020 16:47:27
	(b) (4)	

US3732249

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:34:18

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User accepted default value 'Pre-Dose (PREDOSE)'	Lauren Arnett (b) (4) (b) (4)	02 Sep 2020 16:47:27

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:34:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	02 Sep 2020 16:47:27



**US3732249**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:34:18**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '01 Sep 2020'	Lauren Arnett (b) (4)	02 Sep 2020 16:47:27

**US3732249**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:34:18**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '14:02'	Lauren Arnett (b) (4)	02 Sep 2020 16:47:27

**US3732249**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User entered '01 Sep 2020 14:02'	System	02 Sep 2020 16:47:27

US3732249

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:34:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '97.7' F	Lauren Arnett (b) (4)	02 Sep 2020 16:47:27

US3732249

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:34:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Oral (Oral)'	Lauren Arnett (b) (4)	02 Sep 2020 16:47:27

**US3732249**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:34:18**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered empty.	Lauren Arnett (b) (4)	02 Sep 2020 16:47:27

**US3732249**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '62'	Lauren Arnett (b) (4)	02 Sep 2020 16:47:27

**US3732249**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User entered 'bpm'	System	02 Sep 2020 16:47:27



US3732249

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:34:18

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '14'	Lauren Arnett (b) (4)	02 Sep 2020 16:47:27

US3732249

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:34:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User entered 'breaths/min'	System	02 Sep 2020 16:47:27

US3732249

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:34:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 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)	02 Sep 2020 18:13:13
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'per investigator NCS not to be an AE as they were asymptomatic' (Site from System).	Lauren Arnett (b) (4) (b) (4)	02 Sep 2020 16:48:30
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	02 Sep 2020 16:47:27
User entered '159'	Lauren Arnett (b) (4) (b) (4)	02 Sep 2020 16:47:27

**US3732249**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User entered 'mmHg'	System	02 Sep 2020 16:47:27

US3732249

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:34:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '76'	Lauren Arnett (b) (4)	02 Sep 2020 16:47:27

US3732249

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:34:18

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User entered 'mmHg'	System	02 Sep 2020 16:47:27

US3732249

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:34:18

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User closed query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Sep 2020 12:20:33
Query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' answered with 'updated' (Site from DM).	Lauren Arnett (b) (4) (b) (4)	22 Sep 2020 22:12:21
User entered missing code ND - Not Done; reason for change Data Entry Error	Lauren Arnett (b) (4) (b) (4)	22 Sep 2020 22:12:15
User opened query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 14:28:41
User entered empty.	Lauren Arnett (b) (4) (b) (4)	02 Sep 2020 16:47:27

**US3732249**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:34:18**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	22 Sep 2020 22:12:15
User entered empty.	Lauren Arnett (b) (4)	02 Sep 2020 16:47:27
	(b) (4)	



US3732249

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:34:18

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User accepted default value 'Post-Dose (POSTDOSE)'	Lauren Arnett (b) (4) (b) (4)	02 Sep 2020 16:47:27

US3732249

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:34:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	02 Sep 2020 16:47:27

US3732249

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:34:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '01 Sep 2020'	Lauren Arnett (b) (4)	02 Sep 2020 16:47:27

**US3732249**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:34:18**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '15:08'	Lauren Arnett (b) (4)	02 Sep 2020 16:47:27

**US3732249**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User entered '01 Sep 2020 15:08'	System	02 Sep 2020 16:47:27

US3732249

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:34:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '98.2' F	Lauren Arnett (b) (4)	02 Sep 2020 16:47:27

US3732249

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:34:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Oral (Oral)'	Lauren Arnett (b) (4)	02 Sep 2020 16:47:27

**US3732249**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:34:18**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered empty.	Lauren Arnett (b) (4)	02 Sep 2020 16:47:27



US3732249

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:34:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '56'	Lauren Arnett (b) (4)	02 Sep 2020 16:47:27

**US3732249**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User entered 'bpm'	System	02 Sep 2020 16:47:27

US3732249

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:34:18

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '16'	Lauren Arnett (b) (4)	02 Sep 2020 16:47:27

**US3732249**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User entered 'breaths/min'	System	02 Sep 2020 16:47:27

US3732249

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:34:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '137'	Lauren Arnett (b) (4)	02 Sep 2020 16:47:27

**US3732249**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User entered 'mmHg'	System	02 Sep 2020 16:47:27

US3732249

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:34:18

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '73'	Lauren Arnett (b) (4)	02 Sep 2020 16:47:27

US3732249

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:34:18

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User entered 'mmHg'	System	02 Sep 2020 16:47:27



**US3732249**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:34:18**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'No (N)'	Lauren Arnett (b) (4)	02 Sep 2020 16:48:35

US3732249

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:34:18

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered empty.	Lauren Arnett (b) (4)	02 Sep 2020 16:48:35

US3732249

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:34:18

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	01 Sep 2020 21:41:58

**US3732249**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:34:18**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered empty.	Lauren Arnett (b) (4)	01 Sep 2020 21:41:58

US3732249

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:34:18

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 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered empty.	Lauren Arnett (b) (4)	01 Sep 2020 21:41:58

US3732249

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:34:18

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User entered 'MRNA-1273 OR PLACEBO'	System	01 Sep 2020 21:41:58

US3732249

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:34:18

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '01 Sep 2020'	Lauren Arnett (b) (4)	01 Sep 2020 21:41:58

**US3732249**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:34:18**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '14:38'	Lauren Arnett (b) (4)	01 Sep 2020 21:41:58



**US3732249**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:34:18**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User entered '01 Sep 2020 14:38'	System	01 Sep 2020 21:41:58

US3732249

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:34:18

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Left Arm (LEFT ARM)'	Lauren Arnett (b) (4)	01 Sep 2020 21:41:58

**US3732249**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:34:18**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User entered 'ONCE'	System	01 Sep 2020 21:41:58

**US3732249**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:34:18**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User entered 'INTRAMUSCULAR'	System	01 Sep 2020 21:41:58

US3732249

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:34:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	02 Sep 2020 16:48:51

**US3732249**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:34:18**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '01 Sep 2020'	Lauren Arnett (b) (4)	02 Sep 2020 16:48:51

**US3732249**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:34:18**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '14:12'	Lauren Arnett (b) (4)	02 Sep 2020 16:48:51

**US3732249**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:34:18**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User entered '01 Sep 2020 14:12'	System	02 Sep 2020 16:48:51



**US3732249**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 10 Jun 2021 09:34:18**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '01 Sep 2020'	Lauren Arnett (b) (4)	02 Sep 2020 16:49:03

**US3732249**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Lauren Arnett (b) (4) (b) (4)	02 Sep 2020 16:49:03

**US3732249**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	02 Sep 2020 16:49:03

**US3732249**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '14:07'	Lauren Arnett (b) (4)	02 Sep 2020 16:49:03

**US3732249**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User entered '01 Sep 2020 14:07'	System	02 Sep 2020 16:49:03

**US3732249**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Lauren Arnett (b) (4) (b) (4)	02 Sep 2020 16:49:03

**US3732249**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'No (N)'	Lauren Arnett (b) (4)	02 Sep 2020 16:49:03

**US3732249**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered empty.	Lauren Arnett (b) (4)	02 Sep 2020 16:49:03



**US3732249**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User entered empty.	System	02 Sep 2020 16:49:03

US3732249

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:34:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	02 Sep 2020 16:49:06

**US3732249**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:34:18**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User entered 'I'	System	02 Sep 2020 16:49:06

US3732249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:34:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
Data entry locked.	System	01 Sep 2020 21:41:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 21:41:58

US3732249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:34:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-01T15:12:45', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '47455019-6944-4803-9c85-7486b9f7469d'	System	01 Sep 2020 22:13:40
User entered 'Yes (Y)'	System	01 Sep 2020 22:13:40

US3732249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:34:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-01T15:12:55', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '47455019-6944-4803-9c85-7486b9f7469d' User entered '98.2'	System	01 Sep 2020 22:13:40
	System	01 Sep 2020 22:13:40

US3732249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:34:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-01T15:13:06', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '47455019-6944-4803-9c85-7486b9f7469d'	System	01 Sep 2020 22:13:40
User entered 'No (N)'	System	01 Sep 2020 22:13:40

**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-01T15:13:37', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '47455019-6944-4803-9c85-7486b9f7469d'	System	01 Sep 2020 22:13:40
User entered '01 Sep 2020 15:13'	System	01 Sep 2020 22:13:40



**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '01 Sep 2020 14:58'	System	01 Sep 2020 21:41:58

**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '01 Sep 2020 17:28'	System	01 Sep 2020 21:41:58

US3732249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:34:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
Data entry locked.	System	01 Sep 2020 21:41:58
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 21:41:58

US3732249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:34:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-01T18:34:17', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '67549491-dcbe-4aa7-a484-ccdd9ab7e2ef'	System	02 Sep 2020 01:34:54
User entered 'Yes (Y)'	System	02 Sep 2020 01:34:54

US3732249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:34:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-01T18:34:28', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '67549491-dcbe-4aa7-a484-ccdd9ab7e2ef' User entered '97.7'	System	02 Sep 2020 01:34:54
	System	02 Sep 2020 01:34:54

US3732249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:34:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-01T18:34:34', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '67549491-dcbe-4aa7-a484-ccdd9ab7e2ef'	System	02 Sep 2020 01:34:54
User entered 'No (N)'	System	02 Sep 2020 01:34:54

**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-01T18:34:51', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '67549491-dcbe-4aa7-a484-ccdd9ab7e2ef'	System	02 Sep 2020 01:34:54
User entered '01 Sep 2020 18:34'	System	02 Sep 2020 01:34:54

**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '01 Sep 2020 18:23'	System	01 Sep 2020 21:41:58



**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 21:41:58

**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
Data entry locked.	System	01 Sep 2020 21:41:58
User entered 'Day 2'	System	01 Sep 2020 21:41:58

US3732249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:34:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-02T12:08:29', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '2ca08bc4-a6c1-47a8-9cb5-474ddcf94f1d'	System	02 Sep 2020 19:09:01
User entered 'Yes (Y)'	System	02 Sep 2020 19:09:01

US3732249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:34:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-02T12:08:39', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '2ca08bc4-a6c1-47a8-9cb5-474ddcf94f1d'	System	02 Sep 2020 19:09:01
User entered '97.1'	System	02 Sep 2020 19:09:01

US3732249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:34:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-02T12:08:47', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '2ca08bc4-a6c1-47a8-9cb5-474ddcf94f1d'	System	02 Sep 2020 19:09:01
User entered 'No (N)'	System	02 Sep 2020 19:09:01

**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-02T12:08:57', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '2ca08bc4-a6c1-47a8-9cb5-474ddcf94f1d'	System	02 Sep 2020 19:09:01
User entered '02 Sep 2020 12:08'	System	02 Sep 2020 19:09:01

**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 21:41:58

**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 21:41:58



US3732249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:34:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
Data entry locked.	System	01 Sep 2020 21:41:58
User entered 'Day 3'	System	01 Sep 2020 21:41:58

US3732249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:34:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-03T12:16:28', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '916344b8-0076-48be-ad77-400461b928b5'	System	03 Sep 2020 19:17:09
User entered 'Yes (Y)'	System	03 Sep 2020 19:17:09

US3732249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:34:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-03T12:16:46', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '916344b8-0076-48be-ad77-400461b928b5'	System	03 Sep 2020 19:17:09
User entered '96.5'	System	03 Sep 2020 19:17:09

US3732249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:34:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-03T12:16:52', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '916344b8-0076-48be-ad77-400461b928b5'	System	03 Sep 2020 19:17:09
User entered 'No (N)'	System	03 Sep 2020 19:17:09

**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-03T12:17:06', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '916344b8-0076-48be-ad77-400461b928b5'	System	03 Sep 2020 19:17:09
User entered '03 Sep 2020 12:17'	System	03 Sep 2020 19:17:09

**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 21:41:58

**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 21:41:58

US3732249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:34:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
Data entry locked.	System	01 Sep 2020 21:41:58
User entered 'Day 4'	System	01 Sep 2020 21:41:58



US3732249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:34:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-04T12:23:09', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'f6ba5636-6504-4d0e-abbf-9692d00bf2cc'	System	04 Sep 2020 19:24:41
User entered 'Yes (Y)'	System	04 Sep 2020 19:24:41

US3732249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:34:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-04T12:24:26', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'f6ba5636-6504-4d0e-abbf-9692d00bf2cc' User entered '97.3'	System	04 Sep 2020 19:24:41
	System	04 Sep 2020 19:24:41

US3732249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:34:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-04T12:24:30', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'f6ba5636-6504-4d0e-abbf-9692d00bf2cc'	System	04 Sep 2020 19:24:41
User entered 'No (N)'	System	04 Sep 2020 19:24:41

US3732249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:34:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-04T12:24:37', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'f6ba5636-6504-4d0e-abbf-9692d00bf2cc'	System	04 Sep 2020 19:24:41
User entered '04 Sep 2020 12:24'	System	04 Sep 2020 19:24:41

**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 21:41:58

**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 21:41:58

US3732249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:34:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
Data entry locked.	System	01 Sep 2020 21:41:58
User entered 'Day 5'	System	01 Sep 2020 21:41:58

US3732249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:34:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-05T12:52:17', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'cc5d5935-34ba-4976-a6e3-ea6ab8dd4851'	System	05 Sep 2020 19:52:43
User entered 'Yes (Y)'	System	05 Sep 2020 19:52:43



US3732249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:34:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-05T12:52:25', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'cc5d5935-34ba-4976-a6e3-ea6ab8dd4851'	System	05 Sep 2020 19:52:43
User entered '96.8'	System	05 Sep 2020 19:52:43

US3732249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:34:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-05T12:52:30', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'cc5d5935-34ba-4976-a6e3-ea6ab8dd4851'	System	05 Sep 2020 19:52:43
User entered 'No (N)'	System	05 Sep 2020 19:52:43

**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-05T12:52:41', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'cc5d5935-34ba-4976-a6e3-ea6ab8dd4851'	System	05 Sep 2020 19:52:43
User entered '05 Sep 2020 12:52'	System	05 Sep 2020 19:52:43

**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 21:41:58

**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 21:41:58

US3732249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:34:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
Data entry locked.	System	01 Sep 2020 21:41:58
User entered 'Day 6'	System	01 Sep 2020 21:41:58

US3732249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:34:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-06T12:43:59', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '82ad2c93-1ad7-4389-b49b-ba1a3446dc84'	System	06 Sep 2020 19:44:41
User entered 'Yes (Y)'	System	06 Sep 2020 19:44:41

US3732249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:34:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-06T12:44:12', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '82ad2c93-1ad7-4389-b49b-ba1a3446dc84'	System	06 Sep 2020 19:44:41
User entered '97.9'	System	06 Sep 2020 19:44:41



US3732249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:34:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-06T12:44:22', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '82ad2c93-1ad7-4389-b49b-ba1a3446dc84'	System	06 Sep 2020 19:44:41
User entered 'No (N)'	System	06 Sep 2020 19:44:41

US3732249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:34:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-06T12:44:37', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '82ad2c93-1ad7-4389-b49b-ba1a3446dc84'	System	06 Sep 2020 19:44:41
User entered '06 Sep 2020 12:44'	System	06 Sep 2020 19:44:41

**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 21:41:58

**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 21:41:58

US3732249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:34:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
Data entry locked.	System	01 Sep 2020 21:41:58
User entered 'Day 7'	System	01 Sep 2020 21:41:58

US3732249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:34:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-07T12:01:54', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '8802c34a-6d71-4ef8-8bdb-ae3aebc60278'	System	07 Sep 2020 19:03:07
User entered 'Yes (Y)'	System	07 Sep 2020 19:03:07

US3732249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:34:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-07T12:02:40', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '8802c34a-6d71-4ef8-8bdb-ae3aebc60278'	System	07 Sep 2020 19:03:07
User entered '96.5'	System	07 Sep 2020 19:03:07

US3732249

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:34:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-07T12:02:46', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '8802c34a-6d71-4ef8-8bdb-ae3aebc60278'	System	07 Sep 2020 19:03:07
User entered 'No (N)'	System	07 Sep 2020 19:03:07



**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-07T12:02:58', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '8802c34a-6d71-4ef8-8bdb-ae3aebc60278'	System	07 Sep 2020 19:03:07
User entered '07 Sep 2020 12:02'	System	07 Sep 2020 19:03:07

**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 21:41:58

**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 21:41:58

US3732249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:34:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
Data entry locked.	System	01 Sep 2020 21:41:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 21:41:58

US3732249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:34:18

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 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-01T15:14:09', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '14d103ed-5364-45af-97df-8576f754ad61'	System	01 Sep 2020 22:14:39
User entered 'None (1)'	System	01 Sep 2020 22:14:39

US3732249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:34:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-01T15:14:15', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '14d103ed-5364-45af-97df-8576f754ad61'	System	01 Sep 2020 22:14:39
User entered 'No (N)'	System	01 Sep 2020 22:14:39

US3732249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:34:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-01T15:14:20', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '14d103ed-5364-45af-97df-8576f754ad61'	System	01 Sep 2020 22:14:39
User entered 'No (N)'	System	01 Sep 2020 22:14:39

US3732249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:34:18

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 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-01T15:14:27', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '14d103ed-5364-45af-97df-8576f754ad61'	System	01 Sep 2020 22:14:39
User entered 'None (1)'	System	01 Sep 2020 22:14:39



US3732249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:34:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-01T15:14:34', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '14d103ed-5364-45af-97df-8576f754ad61'	System	01 Sep 2020 22:14:39
User entered '01 Sep 2020 15:14'	System	01 Sep 2020 22:14:39

**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '01 Sep 2020 14:58'	System	01 Sep 2020 21:41:58

**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '01 Sep 2020 17:28'	System	01 Sep 2020 21:41:58

US3732249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:34:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
Data entry locked.	System	01 Sep 2020 21:41:58
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 21:41:58

US3732249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:34:18

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 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-01T18:34:58', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'cb38850b-343f-4e7f-8e5d-daaf8731d055'	System	02 Sep 2020 01:35:31
User entered 'None (1)'	System	02 Sep 2020 01:35:31

US3732249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:34:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-01T18:35:04', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'cb38850b-343f-4e7f-8e5d-daaf8731d055'	System	02 Sep 2020 01:35:31
User entered 'No (N)'	System	02 Sep 2020 01:35:31

US3732249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:34:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-01T18:35:10', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'cb38850b-343f-4e7f-8e5d-daaf8731d055'	System	02 Sep 2020 01:35:31
User entered 'No (N)'	System	02 Sep 2020 01:35:31

US3732249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:34:18

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 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-01T18:35:18', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'cb38850b-343f-4e7f-8e5d-daaf8731d055'	System	02 Sep 2020 01:35:31
User entered 'None (1)'	System	02 Sep 2020 01:35:31



**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-01T18:35:28', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'cb38850b-343f-4e7f-8e5d-daa8731d055'	System	02 Sep 2020 01:35:31
User entered '01 Sep 2020 18:35'	System	02 Sep 2020 01:35:31

**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '01 Sep 2020 18:23'	System	01 Sep 2020 21:41:58

**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 21:41:58

US3732249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:34:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
Data entry locked.	System	01 Sep 2020 21:41:58
User entered 'Day 2'	System	01 Sep 2020 21:41:58

US3732249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:34:18

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 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-02T12:09:10', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '1dbf595e-bce9-4802-a0af-7747ffd44fa6'	System	02 Sep 2020 19:09:40
User entered 'None (1)'	System	02 Sep 2020 19:09:40

US3732249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:34:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-02T12:09:15', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '1dbf595e-bce9-4802-a0af-7747ffd44fa6'	System	02 Sep 2020 19:09:40
User entered 'No (N)'	System	02 Sep 2020 19:09:40

US3732249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:34:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-02T12:09:21', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '1dbf595e-bce9-4802-a0af-7747ffd44fa6'	System	02 Sep 2020 19:09:40
User entered 'No (N)'	System	02 Sep 2020 19:09:40

US3732249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:34:18

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 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-02T12:09:30', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '1dbf595e-bce9-4802-a0af-7747ffd44fa6'	System	02 Sep 2020 19:09:40
User entered 'None (1)'	System	02 Sep 2020 19:09:40



US3732249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:34:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-02T12:09:36', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '1dbf595e-bce9-4802-a0af-7747ffd44fa6'	System	02 Sep 2020 19:09:40
User entered '02 Sep 2020 12:09'	System	02 Sep 2020 19:09:40

**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 21:41:58

**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 21:41:58

**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
Data entry locked.	System	01 Sep 2020 21:41:58
User entered 'Day 3'	System	01 Sep 2020 21:41:58

US3732249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:34:18

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 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-03T12:17:13', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '5cb41b4a-767c-4076-91d6-da303e3456cf'	System	03 Sep 2020 19:17:40
User entered 'None (1)'	System	03 Sep 2020 19:17:40

US3732249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:34:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-03T12:17:18', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '5cb41b4a-767c-4076-91d6-da303e3456cf'	System	03 Sep 2020 19:17:40
User entered 'No (N)'	System	03 Sep 2020 19:17:40

US3732249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:34:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-03T12:17:24', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '5cb41b4a-767c-4076-91d6-da303e3456cf'	System	03 Sep 2020 19:17:40
User entered 'No (N)'	System	03 Sep 2020 19:17:40

US3732249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:34:18

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 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-03T12:17:32', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '5cb41b4a-767c-4076-91d6-da303e3456cf'	System	03 Sep 2020 19:17:40
User entered 'None (1)'	System	03 Sep 2020 19:17:40



US3732249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:34:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-03T12:17:37', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '5cb41b4a-767c-4076-91d6-da303e3456cf'	System	03 Sep 2020 19:17:40
User entered '03 Sep 2020 12:17'	System	03 Sep 2020 19:17:40

**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 21:41:58

**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 21:41:58

US3732249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:34:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
Data entry locked.	System	01 Sep 2020 21:41:58
User entered 'Day 4'	System	01 Sep 2020 21:41:58

US3732249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:34:18

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 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-04T12:24:43', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '18db80d4-7754-4934-a30b-719a1758013f'	System	04 Sep 2020 19:25:10
User entered 'None (1)'	System	04 Sep 2020 19:25:10

US3732249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:34:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-04T12:24:48', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '18db80d4-7754-4934-a30b-719a1758013f'	System	04 Sep 2020 19:25:10
User entered 'No (N)'	System	04 Sep 2020 19:25:10

US3732249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:34:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-04T12:24:53', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '18db80d4-7754-4934-a30b-719a1758013f'	System	04 Sep 2020 19:25:10
User entered 'No (N)'	System	04 Sep 2020 19:25:10

US3732249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:34:18

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 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-04T12:24:59', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '18db80d4-7754-4934-a30b-719a1758013f'	System	04 Sep 2020 19:25:10
User entered 'None (1)'	System	04 Sep 2020 19:25:10



**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-04T12:25:05', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '18db80d4-7754-4934-a30b-719a1758013f' User entered '04 Sep 2020 12:25'	System	04 Sep 2020 19:25:10
	System	04 Sep 2020 19:25:10

**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 21:41:58

**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 21:41:58

US3732249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:34:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
Data entry locked.	System	01 Sep 2020 21:41:58
User entered 'Day 5'	System	01 Sep 2020 21:41:58

US3732249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:34:18

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 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-05T12:52:49', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '6d2cb36a-e7f7-40da-af82-f7789bedca2c'	System	05 Sep 2020 19:53:19
User entered 'None (1)'	System	05 Sep 2020 19:53:19

US3732249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:34:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-05T12:52:56', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '6d2cb36a-e7f7-40da-af82-f7789bedca2c'	System	05 Sep 2020 19:53:19
User entered 'No (N)'	System	05 Sep 2020 19:53:19

US3732249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:34:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-05T12:53:01', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '6d2cb36a-e7f7-40da-af82-f7789bedca2c'	System	05 Sep 2020 19:53:19
User entered 'No (N)'	System	05 Sep 2020 19:53:19

US3732249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:34:18

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 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-05T12:53:07', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '6d2cb36a-e7f7-40da-af82-f7789bedca2c'	System	05 Sep 2020 19:53:19
User entered 'None (1)'	System	05 Sep 2020 19:53:19



**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-05T12:53:17', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '6d2cb36a-e7f7-40da-af82-f7789bedca2c'	System	05 Sep 2020 19:53:19
User entered '05 Sep 2020 12:53'	System	05 Sep 2020 19:53:19

**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 21:41:58

**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 21:41:58

US3732249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:34:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
Data entry locked.	System	01 Sep 2020 21:41:58
User entered 'Day 6'	System	01 Sep 2020 21:41:58

US3732249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:34:18

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 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-06T12:44:43', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '95f2c6ae-4611-4ea5-b50a-15c9e56d31c8'	System	06 Sep 2020 19:45:09
User entered 'None (1)'	System	06 Sep 2020 19:45:09

US3732249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:34:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-06T12:44:48', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '95f2c6ae-4611-4ea5-b50a-15c9e56d31c8'	System	06 Sep 2020 19:45:09
User entered 'No (N)'	System	06 Sep 2020 19:45:09

US3732249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:34:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-06T12:44:53', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '95f2c6ae-4611-4ea5-b50a-15c9e56d31c8'	System	06 Sep 2020 19:45:09
User entered 'No (N)'	System	06 Sep 2020 19:45:09

US3732249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:34:18

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 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-06T12:44:58', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '95f2c6ae-4611-4ea5-b50a-15c9e56d31c8'	System	06 Sep 2020 19:45:09
User entered 'None (1)'	System	06 Sep 2020 19:45:09



US3732249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:34:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-06T12:45:07', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '95f2c6ae-4611-4ea5-b50a-15c9e56d31c8'	System	06 Sep 2020 19:45:09
User entered '06 Sep 2020 12:45'	System	06 Sep 2020 19:45:09

**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 21:41:58

**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 21:41:58

US3732249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:34:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
Data entry locked.	System	01 Sep 2020 21:41:58
User entered 'Day 7'	System	01 Sep 2020 21:41:58

US3732249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:34:18

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 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-07T12:03:04', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'eb7cf1d0-a5bb-42bf-9d79-47e5860e665c'	System	07 Sep 2020 19:03:36
User entered 'None (1)'	System	07 Sep 2020 19:03:36

US3732249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:34:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-07T12:03:11', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'eb7cf1d0-a5bb-42bf-9d79-47e5860e665c'	System	07 Sep 2020 19:03:36
User entered 'No (N)'	System	07 Sep 2020 19:03:36

US3732249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:34:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-07T12:03:16', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'eb7cf1d0-a5bb-42bf-9d79-47e5860e665c'	System	07 Sep 2020 19:03:36
User entered 'No (N)'	System	07 Sep 2020 19:03:36

US3732249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:34:18

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 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-07T12:03:21', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'eb7cf1d0-a5bb-42bf-9d79-47e5860e665c'	System	07 Sep 2020 19:03:36
User entered 'None (1)'	System	07 Sep 2020 19:03:36



US3732249

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:34:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-07T12:03:32', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'eb7cf1d0-a5bb-42bf-9d79-47e5860e665c'	System	07 Sep 2020 19:03:36
User entered '07 Sep 2020 12:03'	System	07 Sep 2020 19:03:36

**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 21:41:58

**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 21:41:58

US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:34:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
Data entry locked.	System	01 Sep 2020 21:41:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 21:41:58

US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:34:18

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-01T15:14:49', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '5c6229eb-e6c0-4426-8cb8-024320d451bf'	System	01 Sep 2020 22:15:33
User entered 'None (0)'	System	01 Sep 2020 22:15:33

US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:34:18

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-01T15:14:57', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '5c6229eb-e6c0-4426-8cb8-024320d451bf'	System	01 Sep 2020 22:15:33
User entered 'None (0)'	System	01 Sep 2020 22:15:33

US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:34:18

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-01T15:15:01', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '5c6229eb-e6c0-4426-8cb8-024320d451bf'	System	01 Sep 2020 22:15:33
User entered 'None (0)'	System	01 Sep 2020 22:15:33

US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:34:18

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-01T15:15:04', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '5c6229eb-e6c0-4426-8cb8-024320d451bf'	System	01 Sep 2020 22:15:33
User entered 'None (0)'	System	01 Sep 2020 22:15:33



US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:34:18

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-01T15:15:08', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '5c6229eb-e6c0-4426-8cb8-024320d451bf'	System	01 Sep 2020 22:15:33
User entered 'None (0)'	System	01 Sep 2020 22:15:33

**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:34:18**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-01T15:15:13', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '5c6229eb-e6c0-4426-8cb8-024320d451bf'	System	01 Sep 2020 22:15:33
User entered 'None (0)'	System	01 Sep 2020 22:15:33

US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:34:18

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 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-01T15:15:21', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '5c6229eb-e6c0-4426-8cb8-024320d451bf'	System	01 Sep 2020 22:15:33
User entered 'No (N)'	System	01 Sep 2020 22:15:33

**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-01T15:15:28', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '5c6229eb-e6c0-4426-8cb8-024320d451bf'	System	01 Sep 2020 22:15:33
User entered '01 Sep 2020 15:15'	System	01 Sep 2020 22:15:33

**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '01 Sep 2020 14:58'	System	01 Sep 2020 21:41:58

**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '01 Sep 2020 17:28'	System	01 Sep 2020 21:41:58

US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:34:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
Data entry locked.	System	01 Sep 2020 21:41:58
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 21:41:58

US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:34:18

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-01T18:35:35', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '504b9c96-acc3-4359-ab2b-7c455b1bd111'	System	02 Sep 2020 01:36:19
User entered 'None (0)'	System	02 Sep 2020 01:36:19



US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:34:18

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-01T18:35:41', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '504b9c96-acc3-4359-ab2b-7c455b1bd111'	System	02 Sep 2020 01:36:19
User entered 'None (0)'	System	02 Sep 2020 01:36:19

US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:34:18

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-01T18:35:45', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '504b9c96-acc3-4359-ab2b-7c455b1bd111'	System	02 Sep 2020 01:36:19
User entered 'None (0)'	System	02 Sep 2020 01:36:19

US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:34:18

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-01T18:35:49', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '504b9c96-acc3-4359-ab2b-7c455b1bd111'	System	02 Sep 2020 01:36:19
User entered 'None (0)'	System	02 Sep 2020 01:36:19

US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:34:18

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-01T18:35:57', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '504b9c96-acc3-4359-ab2b-7c455b1bd111'	System	02 Sep 2020 01:36:19
User entered 'None (0)'	System	02 Sep 2020 01:36:19

US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:34:18

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-01T18:36:01', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '504b9c96-acc3-4359-ab2b-7c455b1bd111'	System	02 Sep 2020 01:36:19
User entered 'None (0)'	System	02 Sep 2020 01:36:19

US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:34:18

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 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-01T18:36:06', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '504b9c96-acc3-4359-ab2b-7c455b1bd111'	System	02 Sep 2020 01:36:19
User entered 'No (N)'	System	02 Sep 2020 01:36:19

**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-01T18:36:16', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '504b9c96-acc3-4359-ab2b-7c455b1bd111'	System	02 Sep 2020 01:36:19
User entered '01 Sep 2020 18:36'	System	02 Sep 2020 01:36:19

**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '01 Sep 2020 18:23'	System	01 Sep 2020 21:41:58



**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 21:41:58

**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
Data entry locked.	System	01 Sep 2020 21:41:58
User entered 'Day 2'	System	01 Sep 2020 21:41:58

US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:34:18

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-02T12:09:46', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '0bf2c530-6994-4bc3-a706-09ac35b2098d'	System	02 Sep 2020 19:10:28
User entered 'None (0)'	System	02 Sep 2020 19:10:28

US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:34:18

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-02T12:09:53', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '0bf2c530-6994-4bc3-a706-09ac35b2098d'	System	02 Sep 2020 19:10:28
User entered 'None (0)'	System	02 Sep 2020 19:10:28

US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:34:18

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-02T12:09:58', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '0bf2c530-6994-4bc3-a706-09ac35b2098d'	System	02 Sep 2020 19:10:28
User entered 'None (0)'	System	02 Sep 2020 19:10:28

US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:34:18

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-02T12:10:03', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '0bf2c530-6994-4bc3-a706-09ac35b2098d'	System	02 Sep 2020 19:10:28
User entered 'None (0)'	System	02 Sep 2020 19:10:28

US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:34:18

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-02T12:10:07', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '0bf2c530-6994-4bc3-a706-09ac35b2098d'	System	02 Sep 2020 19:10:28
User entered 'None (0)'	System	02 Sep 2020 19:10:28

US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:34:18

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-02T12:10:11', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '0bf2c530-6994-4bc3-a706-09ac35b2098d'	System	02 Sep 2020 19:10:28
User entered 'None (0)'	System	02 Sep 2020 19:10:28



US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:34:18

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 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-02T12:10:16', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '0bf2c530-6994-4bc3-a706-09ac35b2098d'	System	02 Sep 2020 19:10:28
User entered 'No (N)'	System	02 Sep 2020 19:10:28

**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-02T12:10:23', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '0bf2c530-6994-4bc3-a706-09ac35b2098d'	System	02 Sep 2020 19:10:28
User entered '02 Sep 2020 12:10'	System	02 Sep 2020 19:10:28

**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 21:41:58

**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 21:41:58

**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
Data entry locked.	System	01 Sep 2020 21:41:58
User entered 'Day 3'	System	01 Sep 2020 21:41:58

US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:34:18

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-03T12:17:46', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '8f71255d-1687-44d3-9e15-f5b97e36e26e'	System	03 Sep 2020 19:18:26
User entered 'None (0)'	System	03 Sep 2020 19:18:26

US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:34:18

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-03T12:17:51', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '8f71255d-1687-44d3-9e15-f5b97e36e26e'	System	03 Sep 2020 19:18:26
User entered 'None (0)'	System	03 Sep 2020 19:18:26

US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:34:18

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-03T12:17:57', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '8f71255d-1687-44d3-9e15-f5b97e36e26e'	System	03 Sep 2020 19:18:26
User entered 'None (0)'	System	03 Sep 2020 19:18:26



US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:34:18

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-03T12:18:01', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '8f71255d-1687-44d3-9e15-f5b97e36e26e'	System	03 Sep 2020 19:18:26
User entered 'None (0)'	System	03 Sep 2020 19:18:26

**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:34:18**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-03T12:18:05', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '8f71255d-1687-44d3-9e15-f5b97e36e26e'	System	03 Sep 2020 19:18:26
User entered 'None (0)'	System	03 Sep 2020 19:18:26

US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:34:18

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-03T12:18:08', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '8f71255d-1687-44d3-9e15-f5b97e36e26e'	System	03 Sep 2020 19:18:26
User entered 'None (0)'	System	03 Sep 2020 19:18:26

US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:34:18

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 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-03T12:18:13', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '8f71255d-1687-44d3-9e15-f5b97e36e26e'	System	03 Sep 2020 19:18:26
User entered 'No (N)'	System	03 Sep 2020 19:18:26

**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-03T12:18:22', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '8f71255d-1687-44d3-9e15-f5b97e36e26e'	System	03 Sep 2020 19:18:26
User entered '03 Sep 2020 12:18'	System	03 Sep 2020 19:18:26

**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 21:41:58

**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 21:41:58

**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
Data entry locked.	System	01 Sep 2020 21:41:58
User entered 'Day 4'	System	01 Sep 2020 21:41:58



US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:34:18

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-04T12:25:12', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '3e4b92e4-eafb-437d-8a80-27dc7daa4d6d'	System	04 Sep 2020 19:25:45
User entered 'None (0)'	System	04 Sep 2020 19:25:45

US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:34:18

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-04T12:25:17', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '3e4b92e4-eafb-437d-8a80-27dc7daa4d6d'	System	04 Sep 2020 19:25:45
User entered 'None (0)'	System	04 Sep 2020 19:25:45

US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:34:18

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-04T12:25:21', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '3e4b92e4-eafb-437d-8a80-27dc7daa4d6d'	System	04 Sep 2020 19:25:45
User entered 'None (0)'	System	04 Sep 2020 19:25:45

US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:34:18

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-04T12:25:24', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '3e4b92e4-eafb-437d-8a80-27dc7daa4d6d'	System	04 Sep 2020 19:25:45
User entered 'None (0)'	System	04 Sep 2020 19:25:45

US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:34:18

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-04T12:25:28', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '3e4b92e4-eafb-437d-8a80-27dc7daa4d6d'	System	04 Sep 2020 19:25:45
User entered 'None (0)'	System	04 Sep 2020 19:25:45

US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:34:18

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-04T12:25:31', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '3e4b92e4-eafb-437d-8a80-27dc7daa4d6d'	System	04 Sep 2020 19:25:45
User entered 'None (0)'	System	04 Sep 2020 19:25:45

US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:34:18

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 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-04T12:25:35', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '3e4b92e4-eafb-437d-8a80-27dc7daa4d6d'	System	04 Sep 2020 19:25:45
User entered 'No (N)'	System	04 Sep 2020 19:25:45

**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-04T12:25:39', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '3e4b92e4-eafb-437d-8a80-27dc7daa4d6d'	System	04 Sep 2020 19:25:45
User entered '04 Sep 2020 12:25'	System	04 Sep 2020 19:25:45



**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 21:41:58

**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 21:41:58

**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
Data entry locked.	System	01 Sep 2020 21:41:58
User entered 'Day 5'	System	01 Sep 2020 21:41:58

US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:34:18

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-05T12:53:22', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '233f9f29-58ca-4148-92a7-9cf8cf347d67'	System	05 Sep 2020 19:54:04
User entered 'None (0)'	System	05 Sep 2020 19:54:04

US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:34:18

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-05T12:53:27', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '233f9f29-58ca-4148-92a7-9cf8cf347d67'	System	05 Sep 2020 19:54:04
User entered 'None (0)'	System	05 Sep 2020 19:54:04

US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:34:18

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-05T12:53:31', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '233f9f29-58ca-4148-92a7-9cf8cf347d67'	System	05 Sep 2020 19:54:04
User entered 'None (0)'	System	05 Sep 2020 19:54:04

US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:34:18

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-05T12:53:36', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '233f9f29-58ca-4148-92a7-9cf8cf347d67'	System	05 Sep 2020 19:54:04
User entered 'None (0)'	System	05 Sep 2020 19:54:04

US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:34:18

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-05T12:53:39', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '233f9f29-58ca-4148-92a7-9cf8cf347d67'	System	05 Sep 2020 19:54:04
User entered 'None (0)'	System	05 Sep 2020 19:54:04



**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:34:18**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-05T12:53:44', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '233f9f29-58ca-4148-92a7-9cf8cf347d67'	System	05 Sep 2020 19:54:04
User entered 'None (0)'	System	05 Sep 2020 19:54:04

US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:34:18

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 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-05T12:53:55', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '233f9f29-58ca-4148-92a7-9cf8cf347d67'	System	05 Sep 2020 19:54:04
User entered 'No (N)'	System	05 Sep 2020 19:54:04

US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:34:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-05T12:54:01', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '233f9f29-58ca-4148-92a7-9cf8cf347d67'	System	05 Sep 2020 19:54:04
User entered '05 Sep 2020 12:54'	System	05 Sep 2020 19:54:04

**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 21:41:58

**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 21:41:58

**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
Data entry locked.	System	01 Sep 2020 21:41:58
User entered 'Day 6'	System	01 Sep 2020 21:41:58

US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:34:18

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-06T12:45:13', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'a5747727-34c3-4370-80c6-13c01d69539f' User entered 'None (0)'	System	06 Sep 2020 19:45:52
	System	06 Sep 2020 19:45:52

US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:34:18

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-06T12:45:20', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'a5747727-34c3-4370-80c6-13c01d69539f' User entered 'None (0)'	System	06 Sep 2020 19:45:52
	System	06 Sep 2020 19:45:52



US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:34:18

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-06T12:45:24', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'a5747727-34c3-4370-80c6-13c01d69539f' User entered 'None (0)'	System	06 Sep 2020 19:45:52
	System	06 Sep 2020 19:45:52

US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:34:18

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-06T12:45:29', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'a5747727-34c3-4370-80c6-13c01d69539f' User entered 'None (0)'	System	06 Sep 2020 19:45:52
	System	06 Sep 2020 19:45:52

US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:34:18

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-06T12:45:33', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'a5747727-34c3-4370-80c6-13c01d69539f' User entered 'None (0)'	System	06 Sep 2020 19:45:52
	System	06 Sep 2020 19:45:52

US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:34:18

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-06T12:45:38', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'a5747727-34c3-4370-80c6-13c01d69539f' User entered 'None (0)'	System	06 Sep 2020 19:45:52
	System	06 Sep 2020 19:45:52

US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:34:18

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 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-06T12:45:44', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'a5747727-34c3-4370-80c6-13c01d69539f' User entered 'No (N)'	System	06 Sep 2020 19:45:52
	System	06 Sep 2020 19:45:52

**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-06T12:45:50', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'a5747727-34c3-4370-80c6-13c01d69539f' User entered '06 Sep 2020 12:45'	System	06 Sep 2020 19:45:52
	System	06 Sep 2020 19:45:52

**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 21:41:58

**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 21:41:58



US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:34:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
Data entry locked.	System	01 Sep 2020 21:41:58
User entered 'Day 7'	System	01 Sep 2020 21:41:58

US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:34:18

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-07T12:03:38', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '92ad8e62-8a7c-412b-b14d-1739794159a5'	System	07 Sep 2020 19:04:10
User entered 'None (0)'	System	07 Sep 2020 19:04:10

US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:34:18

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-07T12:03:41', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '92ad8e62-8a7c-412b-b14d-1739794159a5'	System	07 Sep 2020 19:04:10
User entered 'None (0)'	System	07 Sep 2020 19:04:10

US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:34:18

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-07T12:03:45', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '92ad8e62-8a7c-412b-b14d-1739794159a5'	System	07 Sep 2020 19:04:10
User entered 'None (0)'	System	07 Sep 2020 19:04:10

US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:34:18

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-07T12:03:48', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '92ad8e62-8a7c-412b-b14d-1739794159a5'	System	07 Sep 2020 19:04:10
User entered 'None (0)'	System	07 Sep 2020 19:04:10

US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:34:18

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-07T12:03:52', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '92ad8e62-8a7c-412b-b14d-1739794159a5'	System	07 Sep 2020 19:04:10
User entered 'None (0)'	System	07 Sep 2020 19:04:10

US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:34:18

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-07T12:03:55', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '92ad8e62-8a7c-412b-b14d-1739794159a5'	System	07 Sep 2020 19:04:10
User entered 'None (0)'	System	07 Sep 2020 19:04:10

US3732249

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:34:18

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 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-07T12:04:01', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '92ad8e62-8a7c-412b-b14d-1739794159a5'	System	07 Sep 2020 19:04:10
User entered 'No (N)'	System	07 Sep 2020 19:04:10



**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-07T12:04:05', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '92ad8e62-8a7c-412b-b14d-1739794159a5'	System	07 Sep 2020 19:04:10
User entered '07 Sep 2020 12:04'	System	07 Sep 2020 19:04:10

**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 21:41:58

**US3732249**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 21:41:58

**US3732249**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:34:18**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Yes (Y)'	Linda Vega (b) (4)	09 Sep 2020 00:33:07

**US3732249**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:34:18**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '08 Sep 2020'	Linda Vega (b) (4)	09 Sep 2020 00:33:07

**US3732249**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:34:18**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Contact Made (CONTACT MADE)'	Linda Vega (b) (4)	09 Sep 2020 00:33:07

**US3732249**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:34:18**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered empty.	Linda Vega (b) (4)	09 Sep 2020 00:33:07

**US3732249**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:34:18**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Yes (Y)'	Linda Vega (b) (4)	09 Sep 2020 00:33:11



**US3732249**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:34:18**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User entered 'I'	System	09 Sep 2020 00:33:11

**US3732249**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:34:18**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 21:23:35

**US3732249**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:34:18**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '15 Sep 2020'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 21:23:35

**US3732249**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:34:18**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 21:23:35

**US3732249**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:34:18**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 21:23:35

**US3732249**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:34:18**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 21:23:43

**US3732249**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:34:18**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User entered 'I'	System	15 Sep 2020 21:23:43

**US3732249**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:34:18**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Yes (Y)'	(b) (4) Sylvia Lindholm (b) (4)	23 Sep 2020 00:05:18



**US3732249**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:34:18**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '22 Sep 2020'	(b) (4) Sylvia Lindholm (b) (4)	23 Sep 2020 00:05:18

**US3732249**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:34:18**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sylvia Lindholm (b) (4)	23 Sep 2020 00:05:18

US3732249

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:34:18

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered empty.	(b) (4) Sylvia Lindholm (b) (4)	23 Sep 2020 00:05:18

**US3732249**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:34:18**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Yes (Y)'	(b) (4) Sylvia Lindholm (b) (4)	23 Sep 2020 00:05:23

**US3732249**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:34:18**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User entered 'I'	System	23 Sep 2020 00:05:23

**US3732249**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:34:18**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	29 Sep 2020 19:03:48

**US3732249**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '29 Sep 2020'	Lauren Arnett (b) (4)	29 Sep 2020 19:03:48

**US3732249**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:34:18**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Clinic (Clinic)'	Lauren Arnett (b) (4)	29 Sep 2020 19:03:48



**US3732249**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:34:18**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User entered 'VISIT2'	System	29 Sep 2020 19:03:48

US3732249

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:34:18

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User accepted default value 'Pre-Dose (PREDOSE)'	Lauren Arnett (b) (4)	29 Sep 2020 19:04:51
	(b) (4)	

**US3732249**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	29 Sep 2020 19:04:51

**US3732249**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:34:18**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '29 Sep 2020'	Lauren Arnett (b) (4)	29 Sep 2020 19:04:51

**US3732249**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:34:18**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '10:30'	Lauren Arnett (b) (4)	29 Sep 2020 19:04:51

**US3732249**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User entered '29 Sep 2020 10:30'	System	29 Sep 2020 19:04:51

US3732249

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:34:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '98.1' F	Lauren Arnett (b) (4)	29 Sep 2020 19:04:51

**US3732249**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Oral (Oral)'	Lauren Arnett (b) (4)	29 Sep 2020 19:04:51



**US3732249**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:34:18**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered empty.	Lauren Arnett (b) (4)	29 Sep 2020 19:04:51

**US3732249**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '59'	Lauren Arnett (b) (4)	29 Sep 2020 19:04:51

**US3732249**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User entered 'bpm'	System	29 Sep 2020 19:04:51

**US3732249**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '15'	Lauren Arnett (b) (4)	29 Sep 2020 19:04:51

US3732249

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:34:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User entered 'breaths/min'	System	29 Sep 2020 19:04:51

US3732249

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:34:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '140'	Lauren Arnett (b) (4)	29 Sep 2020 19:04:51

**US3732249**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User entered 'mmHg'	System	29 Sep 2020 19:04:51

US3732249

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:34:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '76'	Lauren Arnett (b) (4)	29 Sep 2020 19:04:51



US3732249

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:34:18

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User entered 'mmHg'	System	29 Sep 2020 19:04:51

US3732249

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:34:18

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User accepted default value 'Post-Dose (POSTDOSE)'	Lauren Arnett (b) (4) (b) (4)	29 Sep 2020 19:04:51

**US3732249**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	29 Sep 2020 19:04:51

**US3732249**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:34:18**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '29 Sep 2020'	Lauren Arnett (b) (4)	29 Sep 2020 19:04:51

**US3732249**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:34:18**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '11:40'	Lauren Arnett (b) (4)	29 Sep 2020 19:04:51

**US3732249**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User entered '29 Sep 2020 11:40'	System	29 Sep 2020 19:04:51

US3732249

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:34:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '98.3' F	Lauren Arnett (b) (4)	29 Sep 2020 19:04:51

US3732249

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:34:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Oral (Oral)'	Lauren Arnett (b) (4)	29 Sep 2020 19:04:51



**US3732249**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:34:18**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered empty.	Lauren Arnett (b) (4)	29 Sep 2020 19:04:51

**US3732249**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '55'	Lauren Arnett (b) (4)	29 Sep 2020 19:04:51

**US3732249**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User entered 'bpm'	System	29 Sep 2020 19:04:51

**US3732249**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '16'	Lauren Arnett (b) (4)	29 Sep 2020 19:04:51

US3732249

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:34:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User entered 'breaths/min'	System	29 Sep 2020 19:04:51

US3732249

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:34:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '141'	Lauren Arnett (b) (4)	29 Sep 2020 19:04:51

**US3732249**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User entered 'mmHg'	System	29 Sep 2020 19:04:51

US3732249

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:34:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '79'	Lauren Arnett (b) (4)	29 Sep 2020 19:04:51



US3732249

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:34:18

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User entered 'mmHg'	System	29 Sep 2020 19:04:51

**US3732249**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:34:18**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	29 Sep 2020 19:05:04

**US3732249**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:34:18**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '29 Sep 2020'	Lauren Arnett (b) (4)	29 Sep 2020 19:05:04

**US3732249**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:34:18**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Yes (Y)'	Amara Yilmaz (b) (4)	29 Sep 2020 18:13:54

**US3732249**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:34:18**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered empty.	Amara Yilmaz (b) (4)	29 Sep 2020 18:13:54

US3732249

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:34:18

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 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered empty.	Amara Yilmaz (b) (4)	29 Sep 2020 18:13:54

**US3732249**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:34:18**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User entered 'MRNA-1273 OR PLACEBO'	System	29 Sep 2020 18:13:54

US3732249

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:34:18

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '29 Sep 2020'	Amara Yilmaz (b) (4)	29 Sep 2020 18:13:54



US3732249

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:34:18

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '11:10'	Amara Yilmaz (b) (4)	29 Sep 2020 18:13:54

**US3732249**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:34:18**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User entered '29 Sep 2020 11:10'	System	29 Sep 2020 18:13:54

US3732249

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:34:18

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Left Arm (LEFT ARM)'	Amara Yilmaz (b) (4)	29 Sep 2020 18:13:54

US3732249

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:34:18

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User entered 'ONCE'	System	29 Sep 2020 18:13:54

**US3732249**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:34:18**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User entered 'INTRAMUSCULAR'	System	29 Sep 2020 18:13:54

US3732249

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:34:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	29 Sep 2020 19:05:21

US3732249

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:34:18

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User closed query 'Per GCL Lab Recon: GCL received an unscheduled sample for Immunogenicity Assessment dated 29-SEP-2020. However, this date matches V2D29 in EDC. Please confirm the unscheduled sample belongs to the scheduled visit with the matching date in EDC.' (Site from DM). Query 'Per GCL Lab Recon: GCL received an unscheduled sample for Immunogenicity Assessment dated 29-SEP-2020. However, this date matches V2D29 in EDC. Please confirm the unscheduled sample belongs to the scheduled visit with the matching date in EDC.' answered with 'Unscheduled sample with date 29-SEP-2020 belongs to Day 29 visit. Site ran out of Day 29 kits, therefore an Unscheduled Visit kit was used to complete the Day 29 visit.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 16:51:02
User opened query 'Per GCL Lab Recon: GCL received an unscheduled sample for Immunogenicity Assessment dated 29-SEP-2020. However, this date matches V2D29 in EDC. Please confirm the unscheduled sample belongs to the scheduled visit with the matching date in EDC.' (Site from DM). User entered '29 Sep 2020'	(b) (4), (b) (6)	02 Nov 2020 21:33:16
	(b) (4), (b) (6)	23 Oct 2020 14:17:32
	Lauren Arnett (b) (4)	29 Sep 2020 19:05:21

**US3732249**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:34:18**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '10:45'	Lauren Arnett (b) (4)	29 Sep 2020 19:05:21



**US3732249**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:34:18**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User entered '29 Sep 2020 10:45'	System	29 Sep 2020 19:05:21

US3732249

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:34:18

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User closed query 'Per GCL Lab Recon: GCL has this sample as an Unscheduled. Please confirm that 29SEP2020 is for Day 29 or update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Nov 2020 15:42:15
Query 'Per GCL Lab Recon: GCL has this sample as an Unscheduled. Please confirm that 29SEP2020 is for Day 29 or update accordingly.' answered with 'Date is correct for Day 29 visit. Site ran out of Day 29 kits, therefore an Unscheduled Visit kit was used to complete the Day 29 visit.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 21:32:33
User opened query 'Per GCL Lab Recon: GCL has this sample as an Unscheduled. Please confirm that 29SEP2020 is for Day 29 or update accordingly.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 10:34:29
User entered '29 Sep 2020'	Lauren Arnett (b) (4) (b) (4)	29 Sep 2020 19:05:33

**US3732249**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Lauren Arnett (b) (4) (b) (4)	29 Sep 2020 19:05:33

**US3732249**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	29 Sep 2020 19:05:33

**US3732249**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '10:39'	Lauren Arnett (b) (4)	29 Sep 2020 19:05:33

US3732249

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:34:18

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 29SEP2020 is recorded under Visit2 Day29 visit in EDC, however the same is reported under Unscheduled visit dated 29 SEP 2020 in PPD Central lab. Please reconcile ' canceled (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 06:39:46
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 29SEP2020 is recorded under Visit2 Day29 visit in EDC, however the same is reported under Unscheduled visit dated 29 SEP 2020 in PPD Central lab. Please reconcile ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 06:23:42
User entered '29 Sep 2020 10:39'	System	29 Sep 2020 19:05:33

**US3732249**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Lauren Arnett (b) (4) (b) (4)	29 Sep 2020 19:05:33

**US3732249**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'No (N)'	Lauren Arnett (b) (4)	29 Sep 2020 19:05:33



**US3732249**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:34:18**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered empty.	Lauren Arnett (b) (4)	29 Sep 2020 19:05:33

**US3732249**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User entered empty.	System	29 Sep 2020 19:05:33

**US3732249**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:34:18**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	29 Sep 2020 19:05:37

**US3732249**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:34:18**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User entered 'I'	System	29 Sep 2020 19:05:37

US3732249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:34:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
Data entry locked.	System	29 Sep 2020 18:13:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 18:13:54

US3732249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:34:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-29T12:28:58', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '8f66b00f-fe8e-47b1-ab84-373ff00d2a2c'	System	29 Sep 2020 19:29:29
User entered 'Yes (Y)'	System	29 Sep 2020 19:29:29

US3732249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:34:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-29T12:29:12', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '8f66b00f-fe8e-47b1-ab84-373ff00d2a2c'	System	29 Sep 2020 19:29:29
User entered '96.7'	System	29 Sep 2020 19:29:29

US3732249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:34:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-29T12:29:17', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '8f66b00f-fe8e-47b1-ab84-373ff00d2a2c'	System	29 Sep 2020 19:29:29
User entered 'No (N)'	System	29 Sep 2020 19:29:29



US3732249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:34:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-29T12:29:27', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '8f66b00f-fe8e-47b1-ab84-373ff00d2a2c'	System	29 Sep 2020 19:29:29
User entered '29 Sep 2020 12:29'	System	29 Sep 2020 19:29:29

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '29 Sep 2020 11:30'	System	29 Sep 2020 18:13:54

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '29 Sep 2020 14:00'	System	29 Sep 2020 18:13:54

US3732249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:34:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
Data entry locked.	System	29 Sep 2020 18:13:54
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 18:13:54

US3732249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:34:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-29T16:47:58', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '46acf128-0ffa-411d-9b58-e17d541b04a1'	System	29 Sep 2020 23:48:34
User entered 'Yes (Y)'	System	29 Sep 2020 23:48:34

US3732249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:34:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-29T16:48:07', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '46acf128-0ffa-411d-9b58-e17d541b04a1' User entered '97.1'	System	29 Sep 2020 23:48:34
	System	29 Sep 2020 23:48:34

US3732249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:34:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-29T16:48:13', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '46acf128-0ffa-411d-9b58-e17d541b04a1'	System	29 Sep 2020 23:48:34
User entered 'No (N)'	System	29 Sep 2020 23:48:34

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-29T16:48:28', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '46acf128-0ffa-411d-9b58-e17d541b04a1'	System	29 Sep 2020 23:48:34
User entered '29 Sep 2020 16:48'	System	29 Sep 2020 23:48:34



**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '29 Sep 2020 14:55'	System	29 Sep 2020 18:13:54

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 18:13:54

US3732249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:34:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
Data entry locked.	System	29 Sep 2020 18:13:54
User entered 'Day 2'	System	29 Sep 2020 18:13:54

US3732249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:34:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-30T14:44:48', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'd9658f29-a8bd-4ef6-9084-626d4d5849e3'	System	30 Sep 2020 21:45:31
User entered 'Yes (Y)'	System	30 Sep 2020 21:45:31

US3732249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:34:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-30T14:45:10', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'd9658f29-a8bd-4ef6-9084-626d4d5849e3'	System	30 Sep 2020 21:45:31
User entered '97.4'	System	30 Sep 2020 21:45:31

US3732249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:34:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-30T14:45:14', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'd9658f29-a8bd-4ef6-9084-626d4d5849e3'	System	30 Sep 2020 21:45:31
User entered 'No (N)'	System	30 Sep 2020 21:45:31

US3732249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:34:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-30T14:45:25', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'd9658f29-a8bd-4ef6-9084-626d4d5849e3'	System	30 Sep 2020 21:45:31
User entered '30 Sep 2020 14:45'	System	30 Sep 2020 21:45:31

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 18:13:54



**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 18:13:54

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
Data entry locked.	System	29 Sep 2020 18:13:54
User entered 'Day 3'	System	29 Sep 2020 18:13:54

US3732249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:34:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-01T13:24:34', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '931a4ca4-6f09-4d88-9896-4f719bcbd640'	System	01 Oct 2020 20:25:01
User entered 'Yes (Y)'	System	01 Oct 2020 20:25:01

US3732249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:34:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-01T13:24:44', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '931a4ca4-6f09-4d88-9896-4f719bcbd640'	System	01 Oct 2020 20:25:01
User entered '97.4'	System	01 Oct 2020 20:25:01

US3732249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:34:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-01T13:24:49', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '931a4ca4-6f09-4d88-9896-4f719bcbd640'	System	01 Oct 2020 20:25:01
User entered 'No (N)'	System	01 Oct 2020 20:25:01

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-01T13:24:58', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '931a4ca4-6f09-4d88-9896-4f719bcbd640'	System	01 Oct 2020 20:25:01
User entered '01 Oct 2020 13:24'	System	01 Oct 2020 20:25:01

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 18:13:54

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 18:13:54



US3732249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:34:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
Data entry locked.	System	29 Sep 2020 18:13:54
User entered 'Day 4'	System	29 Sep 2020 18:13:54

US3732249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:34:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-02T14:10:50', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '50bc5c72-fb5f-4380-88f8-05edd2791621'	System	02 Oct 2020 21:11:54
User entered 'Yes (Y)'	System	02 Oct 2020 21:11:54

US3732249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:34:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-02T14:11:38', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '50bc5c72-fb5f-4380-88f8-05edd2791621'	System	02 Oct 2020 21:11:54
User entered '98.4'	System	02 Oct 2020 21:11:54

US3732249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:34:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-02T14:11:42', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '50bc5c72-fb5f-4380-88f8-05edd2791621'	System	02 Oct 2020 21:11:54
User entered 'No (N)'	System	02 Oct 2020 21:11:54

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-02T14:11:50', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '50bc5c72-fb5f-4380-88f8-05edd2791621'	System	02 Oct 2020 21:11:54
User entered '02 Oct 2020 14:11'	System	02 Oct 2020 21:11:54

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 18:13:54

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 18:13:54

US3732249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:34:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
Data entry locked.	System	29 Sep 2020 18:13:54
User entered 'Day 5'	System	29 Sep 2020 18:13:54



US3732249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:34:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-03T15:49:13', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'c3939717-e704-410a-a452-0e28d23519fc'	System	03 Oct 2020 22:50:37
User entered 'Yes (Y)'	System	03 Oct 2020 22:50:37

US3732249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:34:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-03T15:50:24', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'c3939717-e704-410a-a452-0e28d23519fc'	System	03 Oct 2020 22:50:37
User entered '97.3'	System	03 Oct 2020 22:50:37

US3732249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:34:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-03T15:50:30', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'c3939717-e704-410a-a452-0e28d23519fc'	System	03 Oct 2020 22:50:37
User entered 'No (N)'	System	03 Oct 2020 22:50:37

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-03T15:50:35', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'c3939717-e704-410a-a452-0e28d23519fc'	System	03 Oct 2020 22:50:37
User entered '03 Oct 2020 15:50'	System	03 Oct 2020 22:50:37

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 18:13:54

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 18:13:54

US3732249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:34:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
Data entry locked.	System	29 Sep 2020 18:13:54
User entered 'Day 6'	System	29 Sep 2020 18:13:54

US3732249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:34:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-04T13:07:47', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '1878b77b-e757-4a50-bbbb-4dc3089b8159'	System	04 Oct 2020 20:08:14
User entered 'Yes (Y)'	System	04 Oct 2020 20:08:14



US3732249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:34:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-04T13:07:59', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '1878b77b-e757-4a50-bbbb-4dc3089b8159'	System	04 Oct 2020 20:08:14
User entered '97.8'	System	04 Oct 2020 20:08:14

US3732249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:34:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-04T13:08:03', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '1878b77b-e757-4a50-bbbb-4dc3089b8159'	System	04 Oct 2020 20:08:14
User entered 'No (N)'	System	04 Oct 2020 20:08:14

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-04T13:08:11', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '1878b77b-e757-4a50-bbbb-4dc3089b8159'	System	04 Oct 2020 20:08:14
User entered '04 Oct 2020 13:08'	System	04 Oct 2020 20:08:14

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 18:13:54

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 18:13:54

US3732249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:34:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
Data entry locked.	System	29 Sep 2020 18:13:54
User entered 'Day 7'	System	29 Sep 2020 18:13:54

US3732249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:34:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-05T15:56:09', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '7b36ac0d-41f0-490b-8bd5-6f5d8770eeba'	System	05 Oct 2020 22:57:27
User entered 'Yes (Y)'	System	05 Oct 2020 22:57:27

US3732249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:34:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-05T15:57:11', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '7b36ac0d-41f0-490b-8bd5-6f5d8770eeba'	System	05 Oct 2020 22:57:27
User entered '96.8'	System	05 Oct 2020 22:57:27



US3732249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:34:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-05T15:57:14', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '7b36ac0d-41f0-490b-8bd5-6f5d8770eeba'	System	05 Oct 2020 22:57:27
User entered 'No (N)'	System	05 Oct 2020 22:57:27

US3732249

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:34:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-05T15:57:24', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '7b36ac0d-41f0-490b-8bd5-6f5d8770eeba'	System	05 Oct 2020 22:57:27
User entered '05 Oct 2020 15:57'	System	05 Oct 2020 22:57:27

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 18:13:54

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 18:13:54

US3732249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:34:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
Data entry locked.	System	29 Sep 2020 18:13:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 18:13:54

US3732249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:34:18

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 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-29T12:29:38', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'bc9f6fa7-13af-468c-8790-a523a113b00a'	System	29 Sep 2020 19:29:59
User entered 'None (1)'	System	29 Sep 2020 19:29:59

US3732249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:34:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-29T12:29:43', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'bc9f6fa7-13af-468c-8790-a523a113b00a'	System	29 Sep 2020 19:29:59
User entered 'No (N)'	System	29 Sep 2020 19:29:59

US3732249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:34:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-29T12:29:47', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'bc9f6fa7-13af-468c-8790-a523a113b00a'	System	29 Sep 2020 19:29:59
User entered 'No (N)'	System	29 Sep 2020 19:29:59



US3732249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:34:18

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 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-29T12:29:52', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'bc9f6fa7-13af-468c-8790-a523a113b00a'	System	29 Sep 2020 19:29:59
User entered 'None (1)'	System	29 Sep 2020 19:29:59

US3732249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:34:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-29T12:29:55', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'bc9f6fa7-13af-468c-8790-a523a113b00a'	System	29 Sep 2020 19:29:59
User entered '29 Sep 2020 12:29'	System	29 Sep 2020 19:29:59

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '29 Sep 2020 11:30'	System	29 Sep 2020 18:13:54

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '29 Sep 2020 14:00'	System	29 Sep 2020 18:13:54

US3732249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:34:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
Data entry locked.	System	29 Sep 2020 18:13:54
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 18:13:54

US3732249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:34:18

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 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-29T16:48:36', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '3b81c5da-9d04-4d11-8e50-0839f3a0ccf9'	System	29 Sep 2020 23:49:12
User entered 'None (1)'	System	29 Sep 2020 23:49:12

US3732249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:34:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-29T16:48:41', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '3b81c5da-9d04-4d11-8e50-0839f3a0ccf9'	System	29 Sep 2020 23:49:12
User entered 'No (N)'	System	29 Sep 2020 23:49:12

US3732249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:34:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-29T16:48:46', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '3b81c5da-9d04-4d11-8e50-0839f3a0ccf9'	System	29 Sep 2020 23:49:12
User entered 'No (N)'	System	29 Sep 2020 23:49:12



US3732249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:34:18

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 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-29T16:48:59', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '3b81c5da-9d04-4d11-8e50-0839f3a0ccf9'	System	29 Sep 2020 23:49:12
User entered 'None (1)'	System	29 Sep 2020 23:49:12

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-29T16:49:09', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '3b81c5da-9d04-4d11-8e50-0839f3a0ccf9'	System	29 Sep 2020 23:49:12
User entered '29 Sep 2020 16:49'	System	29 Sep 2020 23:49:12

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '29 Sep 2020 14:55'	System	29 Sep 2020 18:13:54

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 18:13:54

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
Data entry locked.	System	29 Sep 2020 18:13:54
User entered 'Day 2'	System	29 Sep 2020 18:13:54

US3732249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:34:18

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 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-30T14:45:35', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '9b4c52c1-961b-4df2-ac25-36803c21c741'	System	30 Sep 2020 21:45:57
User entered 'None (1)'	System	30 Sep 2020 21:45:57

US3732249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:34:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-30T14:45:40', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '9b4c52c1-961b-4df2-ac25-36803c21c741'	System	30 Sep 2020 21:45:57
User entered 'No (N)'	System	30 Sep 2020 21:45:57

US3732249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:34:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-30T14:45:44', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '9b4c52c1-961b-4df2-ac25-36803c21c741'	System	30 Sep 2020 21:45:57
User entered 'No (N)'	System	30 Sep 2020 21:45:57



US3732249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:34:18

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 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-30T14:45:49', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '9b4c52c1-961b-4df2-ac25-36803c21c741'	System	30 Sep 2020 21:45:57
User entered 'None (1)'	System	30 Sep 2020 21:45:57

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-30T14:45:53', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '9b4c52c1-961b-4df2-ac25-36803c21c741'	System	30 Sep 2020 21:45:57
User entered '30 Sep 2020 14:45'	System	30 Sep 2020 21:45:57

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 18:13:54

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 18:13:54

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
Data entry locked.	System	29 Sep 2020 18:13:54
User entered 'Day 3'	System	29 Sep 2020 18:13:54

US3732249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:34:18

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 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-01T13:25:07', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '1b45999a-1345-49c5-bf60-aafd0a253d86'	System	01 Oct 2020 20:25:40
User entered 'None (1)'	System	01 Oct 2020 20:25:40

US3732249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:34:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-01T13:25:12', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '1b45999a-1345-49c5-bf60-aafd0a253d86'	System	01 Oct 2020 20:25:40
User entered 'No (N)'	System	01 Oct 2020 20:25:40

US3732249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:34:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-01T13:25:18', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '1b45999a-1345-49c5-bf60-aafd0a253d86'	System	01 Oct 2020 20:25:40
User entered 'No (N)'	System	01 Oct 2020 20:25:40



US3732249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:34:18

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 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-01T13:25:29', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '1b45999a-1345-49c5-bf60-aafd0a253d86'	System	01 Oct 2020 20:25:40
User entered 'None (1)'	System	01 Oct 2020 20:25:40

US3732249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:34:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-01T13:25:34', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '1b45999a-1345-49c5-bf60-aafd0a253d86'	System	01 Oct 2020 20:25:40
User entered '01 Oct 2020 13:25'	System	01 Oct 2020 20:25:40

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 18:13:54

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 18:13:54

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
Data entry locked.	System	29 Sep 2020 18:13:54
User entered 'Day 4'	System	29 Sep 2020 18:13:54

US3732249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:34:18

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 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-02T14:11:57', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '7d337572-9d5c-4a33-8c70-efd32dd40f3e'	System	02 Oct 2020 21:12:23
User entered 'None (1)'	System	02 Oct 2020 21:12:23

US3732249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:34:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-02T14:12:01', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '7d337572-9d5c-4a33-8c70-efd32dd40f3e'	System	02 Oct 2020 21:12:23
User entered 'No (N)'	System	02 Oct 2020 21:12:23

US3732249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:34:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-02T14:12:05', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '7d337572-9d5c-4a33-8c70-efd32dd40f3e'	System	02 Oct 2020 21:12:23
User entered 'No (N)'	System	02 Oct 2020 21:12:23



US3732249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:34:18

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 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-02T14:12:14', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '7d337572-9d5c-4a33-8c70-efd32dd40f3e'	System	02 Oct 2020 21:12:23
User entered 'None (1)'	System	02 Oct 2020 21:12:23

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-02T14:12:19', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '7d337572-9d5c-4a33-8c70-efd32dd40f3e'	System	02 Oct 2020 21:12:23
User entered '02 Oct 2020 14:12'	System	02 Oct 2020 21:12:23

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 18:13:54

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 18:13:54

US3732249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:34:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
Data entry locked.	System	29 Sep 2020 18:13:54
User entered 'Day 5'	System	29 Sep 2020 18:13:54

US3732249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:34:18

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 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-03T15:50:40', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'a6d9d0d4-c90f-408b-9fb7-eb4674c02f40'	System	03 Oct 2020 22:51:03
User entered 'None (1)'	System	03 Oct 2020 22:51:03

US3732249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:34:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-03T15:50:44', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'a6d9d0d4-c90f-408b-9fb7-eb4674c02f40'	System	03 Oct 2020 22:51:03
User entered 'No (N)'	System	03 Oct 2020 22:51:03

US3732249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:34:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-03T15:50:49', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'a6d9d0d4-c90f-408b-9fb7-eb4674c02f40'	System	03 Oct 2020 22:51:03
User entered 'No (N)'	System	03 Oct 2020 22:51:03



US3732249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:34:18

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 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-03T15:50:53', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'a6d9d0d4-c90f-408b-9fb7-eb4674c02f40'	System	03 Oct 2020 22:51:03
User entered 'None (1)'	System	03 Oct 2020 22:51:03

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-03T15:50:58', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'a6d9d0d4-c90f-408b-9fb7-eb4674c02f40'	System	03 Oct 2020 22:51:03
User entered '03 Oct 2020 15:50'	System	03 Oct 2020 22:51:03

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 18:13:54

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 18:13:54

US3732249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:34:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
Data entry locked.	System	29 Sep 2020 18:13:54
User entered 'Day 6'	System	29 Sep 2020 18:13:54

US3732249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:34:18

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 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-04T13:08:16', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '4e792242-c95d-449c-becb-ecdd9b00dab1'	System	04 Oct 2020 20:08:46
User entered 'None (1)'	System	04 Oct 2020 20:08:46

US3732249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:34:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-04T13:08:22', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '4e792242-c95d-449c-becb-ecdd9b00dab1'	System	04 Oct 2020 20:08:46
User entered 'No (N)'	System	04 Oct 2020 20:08:46

US3732249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:34:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-04T13:08:25', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '4e792242-c95d-449c-becb-ecdd9b00dab1'	System	04 Oct 2020 20:08:46
User entered 'No (N)'	System	04 Oct 2020 20:08:46



US3732249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:34:18

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 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-04T13:08:34', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '4e792242-c95d-449c-becb-ecdd9b00dab1'	System	04 Oct 2020 20:08:46
User entered 'None (1)'	System	04 Oct 2020 20:08:46

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-04T13:08:43', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '4e792242-c95d-449c-becb-ecdd9b00dab1' User entered '04 Oct 2020 13:08'	System	04 Oct 2020 20:08:46
	System	04 Oct 2020 20:08:46

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 18:13:54

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 18:13:54

US3732249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:34:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
Data entry locked.	System	29 Sep 2020 18:13:54
User entered 'Day 7'	System	29 Sep 2020 18:13:54

US3732249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:34:18

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 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-05T15:57:31', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '8f286236-5809-4adf-b636-e99599f89cf2'	System	05 Oct 2020 22:57:49
User entered 'None (1)'	System	05 Oct 2020 22:57:49

US3732249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:34:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-05T15:57:34', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '8f286236-5809-4adf-b636-e99599f89cf2'	System	05 Oct 2020 22:57:49
User entered 'No (N)'	System	05 Oct 2020 22:57:49

US3732249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:34:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-05T15:57:38', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '8f286236-5809-4adf-b636-e99599f89cf2'	System	05 Oct 2020 22:57:49
User entered 'No (N)'	System	05 Oct 2020 22:57:49



US3732249

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:34:18

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 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-05T15:57:43', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '8f286236-5809-4adf-b636-e99599f89cf2'	System	05 Oct 2020 22:57:49
User entered 'None (1)'	System	05 Oct 2020 22:57:49

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-05T15:57:47', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '8f286236-5809-4adf-b636-e99599f89cf2'	System	05 Oct 2020 22:57:49
User entered '05 Oct 2020 15:57'	System	05 Oct 2020 22:57:49

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 18:13:54

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 18:13:54

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
Data entry locked.	System	29 Sep 2020 18:13:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 18:13:54

US3732249

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:34:18

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-29T12:30:02', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '8d76feed-f436-4884-863b-28aef1a94399'	System	29 Sep 2020 19:30:36
User entered 'None (0)'	System	29 Sep 2020 19:30:36

US3732249

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:34:18

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-29T12:30:08', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '8d76feed-f436-4884-863b-28aef1a94399'	System	29 Sep 2020 19:30:36
User entered 'None (0)'	System	29 Sep 2020 19:30:36

US3732249

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:34:18

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-29T12:30:12', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '8d76feed-f436-4884-863b-28aef1a94399'	System	29 Sep 2020 19:30:36
User entered 'None (0)'	System	29 Sep 2020 19:30:36



US3732249

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:34:18

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-29T12:30:15', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '8d76feed-f436-4884-863b-28aef1a94399'	System	29 Sep 2020 19:30:36
User entered 'None (0)'	System	29 Sep 2020 19:30:36

US3732249

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:34:18

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-29T12:30:18', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '8d76feed-f436-4884-863b-28aef1a94399'	System	29 Sep 2020 19:30:36
User entered 'None (0)'	System	29 Sep 2020 19:30:36

US3732249

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:34:18

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-29T12:30:21', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '8d76feed-f436-4884-863b-28aef1a94399'	System	29 Sep 2020 19:30:36
User entered 'None (0)'	System	29 Sep 2020 19:30:36

US3732249

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:34:18

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 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-29T12:30:26', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '8d76feed-f436-4884-863b-28aef1a94399'	System	29 Sep 2020 19:30:36
User entered 'No (N)'	System	29 Sep 2020 19:30:36

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-29T12:30:30', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '8d76feed-f436-4884-863b-28aef1a94399'	System	29 Sep 2020 19:30:36
User entered '29 Sep 2020 12:30'	System	29 Sep 2020 19:30:36

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '29 Sep 2020 11:30'	System	29 Sep 2020 18:13:54

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '29 Sep 2020 14:00'	System	29 Sep 2020 18:13:54

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
Data entry locked.	System	29 Sep 2020 18:13:54
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 18:13:54



US3732249

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:34:18

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-29T16:49:14', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '35557a91-e693-4117-874b-b6aa4933c721'	System	29 Sep 2020 23:49:40
User entered 'None (0)'	System	29 Sep 2020 23:49:40

US3732249

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:34:18

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-29T16:49:17', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '35557a91-e693-4117-874b-b6aa4933c721' User entered 'None (0)'	System	29 Sep 2020 23:49:40
	System	29 Sep 2020 23:49:40

US3732249

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:34:18

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-29T16:49:20', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '35557a91-e693-4117-874b-b6aa4933c721' User entered 'None (0)'	System	29 Sep 2020 23:49:40
	System	29 Sep 2020 23:49:40

US3732249

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:34:18

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-29T16:49:23', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '35557a91-e693-4117-874b-b6aa4933c721' User entered 'None (0)'	System	29 Sep 2020 23:49:40
	System	29 Sep 2020 23:49:40

US3732249

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:34:18

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-29T16:49:26', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '35557a91-e693-4117-874b-b6aa4933c721' User entered 'None (0)'	System	29 Sep 2020 23:49:40
	System	29 Sep 2020 23:49:40

US3732249

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:34:18

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-29T16:49:29', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '35557a91-e693-4117-874b-b6aa4933c721'	System	29 Sep 2020 23:49:40
User entered 'None (0)'	System	29 Sep 2020 23:49:40

US3732249

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:34:18

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 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-29T16:49:34', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '35557a91-e693-4117-874b-b6aa4933c721'	System	29 Sep 2020 23:49:40
User entered 'No (N)'	System	29 Sep 2020 23:49:40

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-29T16:49:37', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '35557a91-e693-4117-874b-b6aa4933c721' User entered '29 Sep 2020 16:49'	System	29 Sep 2020 23:49:40
	System	29 Sep 2020 23:49:40



**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '29 Sep 2020 14:55'	System	29 Sep 2020 18:13:54

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 18:13:54

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
Data entry locked.	System	29 Sep 2020 18:13:54
User entered 'Day 2'	System	29 Sep 2020 18:13:54

US3732249

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:34:18

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-30T14:45:59', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'f9f15fe2-06ba-4faf-977b-8f67af4f975b'	System	30 Sep 2020 21:46:39
User entered 'None (0)'	System	30 Sep 2020 21:46:39

US3732249

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:34:18

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-30T14:46:03', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'f9f15fe2-06ba-4faf-977b-8f67af4f975b'	System	30 Sep 2020 21:46:39
User entered 'None (0)'	System	30 Sep 2020 21:46:39

US3732249

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:34:18

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-30T14:46:08', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'f9f15fe2-06ba-4faf-977b-8f67af4f975b'	System	30 Sep 2020 21:46:39
User entered 'None (0)'	System	30 Sep 2020 21:46:39

US3732249

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:34:18

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-30T14:46:12', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'f9f15fe2-06ba-4faf-977b-8f67af4f975b'	System	30 Sep 2020 21:46:39
User entered 'None (0)'	System	30 Sep 2020 21:46:39

US3732249

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:34:18

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-30T14:46:15', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'f9f15fe2-06ba-4faf-977b-8f67af4f975b'	System	30 Sep 2020 21:46:39
User entered 'None (0)'	System	30 Sep 2020 21:46:39



US3732249

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:34:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-30T14:46:18', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'f9f15fe2-06ba-4faf-977b-8f67af4f975b'	System	30 Sep 2020 21:46:39
User entered 'None (0)'	System	30 Sep 2020 21:46:39

US3732249

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:34:18

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 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-30T14:46:22', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'f9f15fe2-06ba-4faf-977b-8f67af4f975b'	System	30 Sep 2020 21:46:39
User entered 'No (N)'	System	30 Sep 2020 21:46:39

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-09-30T14:46:31', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'f9f15fe2-06ba-4faf-977b-8f67af4f975b'	System	30 Sep 2020 21:46:39
User entered '30 Sep 2020 14:46'	System	30 Sep 2020 21:46:39

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 18:13:54

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 18:13:54

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
Data entry locked.	System	29 Sep 2020 18:13:54
User entered 'Day 3'	System	29 Sep 2020 18:13:54

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:34:18**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-01T13:26:41', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'c1d21c9d-dfff-4ec3-9ca2-0024b96fed09'	System	01 Oct 2020 20:27:10
User entered 'None (0)'	System	01 Oct 2020 20:27:10

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:34:18**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-01T13:26:44', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'c1d21c9d-dfff-4ec3-9ca2-0024b96fed09'	System	01 Oct 2020 20:27:10
User entered 'None (0)'	System	01 Oct 2020 20:27:10



US3732249

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:34:18

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-01T13:26:47', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'c1d21c9d-dfff-4ec3-9ca2-0024b96fed09'	System	01 Oct 2020 20:27:10
User entered 'None (0)'	System	01 Oct 2020 20:27:10

US3732249

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:34:18

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-01T13:26:51', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'c1d21c9d-dfff-4ec3-9ca2-0024b96fed09'	System	01 Oct 2020 20:27:10
User entered 'None (0)'	System	01 Oct 2020 20:27:10

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:34:18**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-01T13:26:54', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'c1d21c9d-dfff-4ec3-9ca2-0024b96fed09'	System	01 Oct 2020 20:27:10
User entered 'None (0)'	System	01 Oct 2020 20:27:10

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:34:18**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-01T13:26:58', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'c1d21c9d-dfff-4ec3-9ca2-0024b96fed09'	System	01 Oct 2020 20:27:10
User entered 'None (0)'	System	01 Oct 2020 20:27:10

US3732249

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:34:18

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 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-01T13:27:02', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'c1d21c9d-dfff-4ec3-9ca2-0024b96fed09'	System	01 Oct 2020 20:27:10
User entered 'No (N)'	System	01 Oct 2020 20:27:10

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-01T13:27:07', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'c1d21c9d-dfff-4ec3-9ca2-0024b96fed09'	System	01 Oct 2020 20:27:10
User entered '01 Oct 2020 13:27'	System	01 Oct 2020 20:27:10

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 18:13:54

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 18:13:54



**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
Data entry locked.	System	29 Sep 2020 18:13:54
User entered 'Day 4'	System	29 Sep 2020 18:13:54

US3732249

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:34:18

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-02T14:12:25', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '57b69590-56b5-428c-9911-fc9d1d85f099'	System	02 Oct 2020 21:12:51
User entered 'None (0)'	System	02 Oct 2020 21:12:51

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:34:18**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-02T14:12:27', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '57b69590-56b5-428c-9911-fc9d1d85f099'	System	02 Oct 2020 21:12:51
User entered 'None (0)'	System	02 Oct 2020 21:12:51

US3732249

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:34:18

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-02T14:12:30', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '57b69590-56b5-428c-9911-fc9d1d85f099'	System	02 Oct 2020 21:12:51
User entered 'None (0)'	System	02 Oct 2020 21:12:51

US3732249

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:34:18

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-02T14:12:33', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '57b69590-56b5-428c-9911-fc9d1d85f099'	System	02 Oct 2020 21:12:51
User entered 'None (0)'	System	02 Oct 2020 21:12:51

US3732249

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:34:18

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-02T14:12:35', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '57b69590-56b5-428c-9911-fc9d1d85f099'	System	02 Oct 2020 21:12:51
User entered 'None (0)'	System	02 Oct 2020 21:12:51

US3732249

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:34:18

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-02T14:12:38', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '57b69590-56b5-428c-9911-fc9d1d85f099'	System	02 Oct 2020 21:12:51
User entered 'None (0)'	System	02 Oct 2020 21:12:51

US3732249

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:34:18

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 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-02T14:12:42', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '57b69590-56b5-428c-9911-fc9d1d85f099'	System	02 Oct 2020 21:12:51
User entered 'No (N)'	System	02 Oct 2020 21:12:51



**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-02T14:12:48', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '57b69590-56b5-428c-9911-fc9d1d85f099'	System	02 Oct 2020 21:12:51
User entered '02 Oct 2020 14:12'	System	02 Oct 2020 21:12:51

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 18:13:54

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 18:13:54

US3732249

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:34:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
Data entry locked.	System	29 Sep 2020 18:13:54
User entered 'Day 5'	System	29 Sep 2020 18:13:54

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:34:18**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-03T15:51:03', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'dd595a1a-56d9-4101-9471-e75fb68b471a'	System	03 Oct 2020 22:51:26
User entered 'None (0)'	System	03 Oct 2020 22:51:26

US3732249

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:34:18

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-03T15:51:05', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'dd595a1a-56d9-4101-9471-e75fb68b471a'	System	03 Oct 2020 22:51:26
User entered 'None (0)'	System	03 Oct 2020 22:51:26

US3732249

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:34:18

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-03T15:51:08', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'dd595a1a-56d9-4101-9471-e75fb68b471a'	System	03 Oct 2020 22:51:26
User entered 'None (0)'	System	03 Oct 2020 22:51:26

US3732249

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:34:18

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-03T15:51:10', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'dd595a1a-56d9-4101-9471-e75fb68b471a'	System	03 Oct 2020 22:51:26
User entered 'None (0)'	System	03 Oct 2020 22:51:26



US3732249

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:34:18

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-03T15:51:12', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'dd595a1a-56d9-4101-9471-e75fb68b471a'	System	03 Oct 2020 22:51:26
User entered 'None (0)'	System	03 Oct 2020 22:51:26

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:34:18**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-03T15:51:15', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'dd595a1a-56d9-4101-9471-e75fb68b471a'	System	03 Oct 2020 22:51:26
User entered 'None (0)'	System	03 Oct 2020 22:51:26

US3732249

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:34:18

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 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-03T15:51:19', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'dd595a1a-56d9-4101-9471-e75fb68b471a'	System	03 Oct 2020 22:51:26
User entered 'No (N)'	System	03 Oct 2020 22:51:26

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-03T15:51:23', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'dd595a1a-56d9-4101-9471-e75fb68b471a'	System	03 Oct 2020 22:51:26
User entered '03 Oct 2020 15:51'	System	03 Oct 2020 22:51:26

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 18:13:54

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 18:13:54

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
Data entry locked.	System	29 Sep 2020 18:13:54
User entered 'Day 6'	System	29 Sep 2020 18:13:54

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:34:18**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-04T13:08:49', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'eeae5155-7dc7-49be-85ed-ebead696e2d2'	System	04 Oct 2020 20:09:23
User entered 'None (0)'	System	04 Oct 2020 20:09:23



US3732249

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:34:18

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-04T13:08:54', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'eeae5155-7dc7-49be-85ed-ebead696e2d2'	System	04 Oct 2020 20:09:23
User entered 'None (0)'	System	04 Oct 2020 20:09:23

US3732249

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:34:18

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-04T13:08:59', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'eeae5155-7dc7-49be-85ed-ebead696e2d2'	System	04 Oct 2020 20:09:23
User entered 'None (0)'	System	04 Oct 2020 20:09:23

US3732249

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:34:18

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-04T13:09:02', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'eeae5155-7dc7-49be-85ed-ebead696e2d2'	System	04 Oct 2020 20:09:23
User entered 'None (0)'	System	04 Oct 2020 20:09:23

US3732249

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:34:18

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-04T13:09:06', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'eeae5155-7dc7-49be-85ed-ebead696e2d2'	System	04 Oct 2020 20:09:23
User entered 'None (0)'	System	04 Oct 2020 20:09:23

US3732249

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:34:18

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-04T13:09:08', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'eeae5155-7dc7-49be-85ed-ebead696e2d2'	System	04 Oct 2020 20:09:23
User entered 'None (0)'	System	04 Oct 2020 20:09:23

US3732249

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:34:18

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 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-04T13:09:13', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'eeae5155-7dc7-49be-85ed-ebead696e2d2'	System	04 Oct 2020 20:09:23
User entered 'No (N)'	System	04 Oct 2020 20:09:23

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-04T13:09:18', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'eeae5155-7dc7-49be-85ed-ebead696e2d2'	System	04 Oct 2020 20:09:23
User entered '04 Oct 2020 13:09'	System	04 Oct 2020 20:09:23

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 18:13:54



**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 18:13:54

US3732249

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:34:18

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
Data entry locked.	System	29 Sep 2020 18:13:54
User entered 'Day 7'	System	29 Sep 2020 18:13:54

US3732249

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:34:18

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-05T15:57:54', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'e715d177-983a-4d76-bd97-0383f0cfa925'	System	05 Oct 2020 22:58:22
User entered 'None (0)'	System	05 Oct 2020 22:58:22

US3732249

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:34:18

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-05T15:57:57', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'e715d177-983a-4d76-bd97-0383f0cfa925'	System	05 Oct 2020 22:58:22
User entered 'None (0)'	System	05 Oct 2020 22:58:22

US3732249

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:34:18

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-05T15:58:00', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'e715d177-983a-4d76-bd97-0383f0cfa925'	System	05 Oct 2020 22:58:22
User entered 'None (0)'	System	05 Oct 2020 22:58:22

US3732249

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:34:18

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-05T15:58:02', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'e715d177-983a-4d76-bd97-0383f0cfa925'	System	05 Oct 2020 22:58:22
User entered 'None (0)'	System	05 Oct 2020 22:58:22

US3732249

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:34:18

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-05T15:58:05', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'e715d177-983a-4d76-bd97-0383f0cfa925'	System	05 Oct 2020 22:58:22
User entered 'None (0)'	System	05 Oct 2020 22:58:22

US3732249

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:34:18

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-05T15:58:07', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'e715d177-983a-4d76-bd97-0383f0cfa925'	System	05 Oct 2020 22:58:22
User entered 'None (0)'	System	05 Oct 2020 22:58:22



US3732249

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:34:18

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 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-05T15:58:12', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'e715d177-983a-4d76-bd97-0383f0cfa925'	System	05 Oct 2020 22:58:22
User entered 'No (N)'	System	05 Oct 2020 22:58:22

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-10-05T15:58:20', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'e715d177-983a-4d76-bd97-0383f0cfa925'	System	05 Oct 2020 22:58:22
User entered '05 Oct 2020 15:58'	System	05 Oct 2020 22:58:22

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 18:13:54

**US3732249**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:34:18**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 18:13:54

**US3732249**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:34:18**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Yes (Y)'	Linda Vega (b) (4)	06 Oct 2020 20:13:52

**US3732249**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:34:18**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '06 Oct 2020'	Linda Vega (b) (4)	06 Oct 2020 20:13:52

**US3732249**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:34:18**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Contact Made (CONTACT MADE)'	Linda Vega (b) (4)	06 Oct 2020 20:13:52

US3732249

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:34:18

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered empty.	Linda Vega (b) (4)	06 Oct 2020 20:13:52



US3732249

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:34:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Yes (Y)'	Linda Vega (b) (4)	06 Oct 2020 20:13:55

**US3732249**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:34:18**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User entered 'I'	System	06 Oct 2020 20:13:55

**US3732249**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:34:18**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Yes (Y)'	Linda Vega (b) (4)	13 Oct 2020 17:05:48

**US3732249**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:34:18**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '13 Oct 2020'	Linda Vega (b) (4)	13 Oct 2020 17:05:48

**US3732249**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:34:18**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Contact Made (CONTACT MADE)'	Linda Vega (b) (4)	13 Oct 2020 17:05:48

**US3732249**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:34:18**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered empty.	Linda Vega (b) (4)	13 Oct 2020 17:05:48

**US3732249**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:34:18**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Yes (Y)'	Linda Vega (b) (4)	13 Oct 2020 17:05:50

**US3732249**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:34:18**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User entered 'I'	System	13 Oct 2020 17:05:50



**US3732249**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:34:18**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Yes (Y)'	Linda Vega (b) (4)	20 Oct 2020 17:43:57

**US3732249**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:34:18**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '20 Oct 2020'	Linda Vega (b) (4)	20 Oct 2020 17:43:57

**US3732249**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:34:18**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Contact Made (CONTACT MADE)'	Linda Vega (b) (4)	20 Oct 2020 17:43:57

**US3732249**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:34:18**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered empty.	Linda Vega (b) (4)	20 Oct 2020 17:43:57

**US3732249**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:34:18**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Yes (Y)'	Linda Vega (b) (4)	20 Oct 2020 17:44:05

**US3732249**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:34:18**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User entered 'I'	System	20 Oct 2020 17:44:05

**US3732249**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:34:18**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 21:34:03

**US3732249**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '30 Oct 2020'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 21:34:03



**US3732249**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:34:18**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 21:34:03

**US3732249**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:34:18**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User entered 'VISIT3'	System	02 Nov 2020 21:34:03

US3732249

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:34:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 21:36:56

**US3732249**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '30 Oct 2020'	(b) (4), (b) (6)	02 Nov 2020 21:36:56

**US3732249**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '13:15'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 21:36:56

**US3732249**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User entered '30 Oct 2020 13:15'	System	02 Nov 2020 21:36:56

US3732249

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:34:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '98.1' F	(b) (4) (b) (4), (b) (6)	02 Nov 2020 21:36:56

US3732249

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:34:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 21:36:56



**US3732249**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 21:36:56

**US3732249**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '60'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 21:36:56

**US3732249**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User entered 'bpm'	System	02 Nov 2020 21:36:56

**US3732249**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '16'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 21:36:56

**US3732249**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User entered 'breaths/min'	System	02 Nov 2020 21:36:56

**US3732249**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '122'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 21:36:56

**US3732249**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User entered 'mmHg'	System	02 Nov 2020 21:36:56

**US3732249**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '65'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 21:36:56



**US3732249**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User entered 'mmHg'	System	02 Nov 2020 21:36:56

**US3732249**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13

**US3732249**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13

**US3732249**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:34:18**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 21:34:26

**US3732249**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:34:18**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 21:34:26

**US3732249**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:34:18**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 21:35:53

**US3732249**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:34:18**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '30 Oct 2020'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 21:35:53

**US3732249**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:34:18**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '13:27'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 21:35:53



**US3732249**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:34:18**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User entered '30 Oct 2020 13:27'	System	02 Nov 2020 21:35:53

**US3732249**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:34:18**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 21:36:14

**US3732249**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:34:18**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User entered 'I'	System	02 Nov 2020 21:36:14

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
Data entry locked.	System	01 Sep 2020 21:41:58
User entered 'Day 64'	System	01 Sep 2020 21:41:58

US3732249

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

[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 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-11-03T19:54:56', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '48a0ec37-af8b-4978-9367-a863beac87fc'	System	04 Nov 2020 03:55:17
User entered 'No (N)'	System	04 Nov 2020 03:55:17

US3732249

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

Have you been exposed to someone with 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 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-11-03T19:54:35', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '48a0ec37-af8b-4978-9367-a863beac87fc'	System	04 Nov 2020 03:55:17
User entered 'No (N)'	System	04 Nov 2020 03:55:17

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-11-03T19:55:13', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '48a0ec37-af8b-4978-9367-a863beac87fc'	System	04 Nov 2020 03:55:17
User entered '03 Nov 2020 19:55:13'	System	04 Nov 2020 03:55:17

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
Data entry locked.	System	01 Sep 2020 21:41:58
User entered '01 Nov 2020 00:01'	System	01 Sep 2020 21:41:58



**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
Data entry locked.	System	01 Sep 2020 21:41:58
User entered '05 Nov 2020 23:59'	System	01 Sep 2020 21:41:58

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
Data entry locked.	System	01 Sep 2020 21:41:58
User entered 'Day 71'	System	01 Sep 2020 21:41:58

US3732249

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

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 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-11-10T16:34:21', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '0e62d067-38b1-4da6-b9d0-1e2e60f5e263'	System	11 Nov 2020 00:34:54
User entered 'No (N)'	System	11 Nov 2020 00:34:54

US3732249

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

Have you been exposed to someone with 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 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-11-10T16:34:32', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '0e62d067-38b1-4da6-b9d0-1e2e60f5e263'	System	11 Nov 2020 00:34:54
User entered 'No (N)'	System	11 Nov 2020 00:34:54

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-11-10T16:34:52', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '0e62d067-38b1-4da6-b9d0-1e2e60f5e263'	System	11 Nov 2020 00:34:54
User entered '10 Nov 2020 16:34:52'	System	11 Nov 2020 00:34:54

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
Data entry locked.	System	01 Sep 2020 21:41:58
User entered '08 Nov 2020 00:01'	System	01 Sep 2020 21:41:58

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
Data entry locked.	System	01 Sep 2020 21:41:58
User entered '12 Nov 2020 23:59'	System	01 Sep 2020 21:41:58

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
Data entry locked.	System	01 Sep 2020 21:41:58
User entered 'Day 78'	System	01 Sep 2020 21:41:58



US3732249

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:34:18

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 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-11-17T12:01:21', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '3db79696-12c6-4556-9104-b0d1b28b83a2'	System	17 Nov 2020 20:01:48
User entered 'No (N)'	System	17 Nov 2020 20:01:48

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Have you been exposed to someone with 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 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-11-17T12:01:31', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '3db79696-12c6-4556-9104-b0d1b28b83a2'	System	17 Nov 2020 20:01:48
User entered 'No (N)'	System	17 Nov 2020 20:01:48

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-11-17T12:01:44', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '3db79696-12c6-4556-9104-b0d1b28b83a2' User entered '17 Nov 2020 12:01:44'	System	17 Nov 2020 20:01:48
	System	17 Nov 2020 20:01:48

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
Data entry locked.	System	01 Sep 2020 21:41:58
User entered '15 Nov 2020 00:01'	System	01 Sep 2020 21:41:58

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 15:51:28
Data entry locked.	System	01 Sep 2020 21:41:58
User entered '19 Nov 2020 23:59'	System	01 Sep 2020 21:41:58

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[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 (f638d9a4fd639462)', Time: '2020-11-23T06:05:04', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '25ccc5d4-af83-489d-aed8-c80f09ddeb3f'	System	23 Nov 2020 14:05:44
User entered 'No (N)'	System	23 Nov 2020 14:05:44

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Have you been exposed to someone with 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 (f638d9a4fd639462)', Time: '2020-11-23T06:05:29', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '25ccc5d4-af83-489d-aed8-c80f09ddeb3f'	System	23 Nov 2020 14:05:44
User entered 'No (N)'	System	23 Nov 2020 14:05:44



**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-11-23T06:05:42', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '25ccc5d4-af83-489d-aed8-c80f09ddeb3f' User entered '23 Nov 2020 06:05:42'	System	23 Nov 2020 14:05:44

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[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 (f638d9a4fd639462)', Time: '2020-11-28T12:19:35', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '198f5337-b6f1-42d3-95dc-10e8bd0d450d'	System	28 Nov 2020 20:20:09
User entered 'No (N)'	System	28 Nov 2020 20:20:09

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

Have you been exposed to someone with 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 (f638d9a4fd639462)', Time: '2020-11-28T12:19:49', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '198f5337-b6f1-42d3-95dc-10e8bd0d450d'	System	28 Nov 2020 20:20:09
User entered 'No (N)'	System	28 Nov 2020 20:20:09

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-11-28T12:20:06', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '198f5337-b6f1-42d3-95dc-10e8bd0d450d'	System	28 Nov 2020 20:20:09
User entered '28 Nov 2020 12:20:06'	System	28 Nov 2020 20:20:09

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 22:05:04



**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[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 (f638d9a4fd639462)', Time: '2020-12-03T10:05:48', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'b6ca1942-4309-4791-b175-15b0a8aebd4a'	System	03 Dec 2020 18:06:15
User entered 'No (N)'	System	03 Dec 2020 18:06:15

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Have you been exposed to someone with 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 (f638d9a4fd639462)', Time: '2020-12-03T10:06:01', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'b6ca1942-4309-4791-b175-15b0a8aebd4a'	System	03 Dec 2020 18:06:15
User entered 'No (N)'	System	03 Dec 2020 18:06:15

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-12-03T10:06:11', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'b6ca1942-4309-4791-b175-15b0a8aebd4a'	System	03 Dec 2020 18:06:15
User entered '03 Dec 2020 10:06:11'	System	03 Dec 2020 18:06:15

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 22:05:04



**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[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 (f638d9a4fd639462)', Time: '2020-12-10T11:14:30', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'b7ac87c6-057d-4515-aed6-0a07aeb11939'	System	10 Dec 2020 19:14:57
User entered 'No (N)'	System	10 Dec 2020 19:14:57

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

Have you been exposed to someone with 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 (f638d9a4fd639462)', Time: '2020-12-10T11:14:42', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'b7ac87c6-057d-4515-aed6-0a07aeb11939'	System	10 Dec 2020 19:14:57
User entered 'No (N)'	System	10 Dec 2020 19:14:57

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-12-10T11:14:54', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'b7ac87c6-057d-4515-aed6-0a07aeb11939' User entered '10 Dec 2020 11:14:54'	System	10 Dec 2020 19:14:57
	System	10 Dec 2020 19:14:57

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[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 (f638d9a4fd639462)', Time: '2020-12-17T11:00:19', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '260e44a8-8f51-4263-889e-f16d6078ee48'	System	17 Dec 2020 19:00:43
User entered 'No (N)'	System	17 Dec 2020 19:00:43

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

Have you been exposed to someone with 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 (f638d9a4fd639462)', Time: '2020-12-17T11:00:24', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '260e44a8-8f51-4263-889e-f16d6078ee48'	System	17 Dec 2020 19:00:43
User entered 'No (N)'	System	17 Dec 2020 19:00:43



**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-12-17T11:00:39', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '260e44a8-8f51-4263-889e-f16d6078ee48'	System	17 Dec 2020 19:00:43
User entered '17 Dec 2020 11:00:39'	System	17 Dec 2020 19:00:43

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[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 (f638d9a4fd639462)', Time: '2020-12-24T15:28:45', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '80a5e289-8c39-4cd5-81a6-fc06a859c69d'	System	24 Dec 2020 23:29:14
User entered 'No (N)'	System	24 Dec 2020 23:29:14

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

Have you been exposed to someone with 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 (f638d9a4fd639462)', Time: '2020-12-24T15:28:57', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '80a5e289-8c39-4cd5-81a6-fc06a859c69d'	System	24 Dec 2020 23:29:14
User entered 'No (N)'	System	24 Dec 2020 23:29:14

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-12-24T15:29:11', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '80a5e289-8c39-4cd5-81a6-fc06a859c69d'	System	24 Dec 2020 23:29:14
User entered '24 Dec 2020 15:29:11'	System	24 Dec 2020 23:29:14

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 22:05:04



**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[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 (f638d9a4fd639462)', Time: '2020-12-31T05:54:08', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'c7935499-0a66-4132-9bc5-fef95009b55e'	System	31 Dec 2020 13:54:54
User entered 'No (N)'	System	31 Dec 2020 13:54:54

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

Have you been exposed to someone with 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 (f638d9a4fd639462)', Time: '2020-12-31T05:54:23', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'c7935499-0a66-4132-9bc5-fef95009b55e'	System	31 Dec 2020 13:54:54
User entered 'No (N)'	System	31 Dec 2020 13:54:54

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2020-12-31T05:54:47', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'c7935499-0a66-4132-9bc5-fef95009b55e'	System	31 Dec 2020 13:54:54
User entered '31 Dec 2020 05:54:47'	System	31 Dec 2020 13:54:54

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 22:05:04



**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[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 (f638d9a4fd639462)', Time: '2021-01-07T14:08:34', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'a4a2627f-bfc6-4b88-b19d-716ec812271f'	System	07 Jan 2021 22:09:17
User entered 'No (N)'	System	07 Jan 2021 22:09:17

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

Have you been exposed to someone with 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 (f638d9a4fd639462)', Time: '2021-01-07T14:08:47', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'a4a2627f-bfc6-4b88-b19d-716ec812271f'	System	07 Jan 2021 22:09:17
User entered 'No (N)'	System	07 Jan 2021 22:09:17

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2021-01-07T14:09:13', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'a4a2627f-bfc6-4b88-b19d-716ec812271f' User entered '07 Jan 2021 14:09:13'	System	07 Jan 2021 22:09:17

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[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 (f638d9a4fd639462)', Time: '2021-01-14T05:53:51', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'b115e00a-e089-472a-8dac-db84338838ce'	System	14 Jan 2021 13:54:17
User entered 'No (N)'	System	14 Jan 2021 13:54:17

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

Have you been exposed to someone with 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 (f638d9a4fd639462)', Time: '2021-01-14T05:53:57', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'b115e00a-e089-472a-8dac-db84338838ce'	System	14 Jan 2021 13:54:17
User entered 'No (N)'	System	14 Jan 2021 13:54:17



**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2021-01-14T05:54:14', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'b115e00a-e089-472a-8dac-db84338838ce' User entered '14 Jan 2021 05:54:14'	System	14 Jan 2021 13:54:17
	System	14 Jan 2021 13:54:17

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[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 (f638d9a4fd639462)', Time: '2021-01-21T14:52:34', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'c0003210-887a-4fbd-837f-20094e919849'	System	21 Jan 2021 22:53:09
User entered 'No (N)'	System	21 Jan 2021 22:53:09

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

Have you been exposed to someone with 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 (f638d9a4fd639462)', Time: '2021-01-21T14:52:47', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'c0003210-887a-4fbd-837f-20094e919849'	System	21 Jan 2021 22:53:09
User entered 'No (N)'	System	21 Jan 2021 22:53:09

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2021-01-21T14:53:06', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'c0003210-887a-4fbd-837f-20094e919849' User entered '21 Jan 2021 14:53:06'	System	21 Jan 2021 22:53:09

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 22:05:04



**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[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 (f638d9a4fd639462)', Time: '2021-01-29T18:08:32', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'fd45c077-fb46-4e73-bdca-5e90e03b721f'	System	30 Jan 2021 02:11:21
User entered 'Yes (Y)'	System	30 Jan 2021 02:11:21

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

Have you been exposed to someone with 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 (f638d9a4fd639462)', Time: '2021-01-29T18:08:41', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'fd45c077-fb46-4e73-bdca-5e90e03b721f' User entered 'No (N)'	System	30 Jan 2021 02:11:21

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2021-01-29T18:08:54', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'fd45c077-fb46-4e73-bdca-5e90e03b721f' User entered 'No (N)'	System	30 Jan 2021 02:11:21

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2021-01-29T18:09:23', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'fd45c077-fb46-4e73-bdca-5e90e03b721f'	System	30 Jan 2021 02:11:21
User entered 'Yes (Y)'	System	30 Jan 2021 02:11:21

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2021-01-29T18:09:39', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'fd45c077-fb46-4e73-bdca-5e90e03b721f'	System	30 Jan 2021 02:11:21
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	30 Jan 2021 02:11:21

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2021-01-29T18:09:47', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'fd45c077-fb46-4e73-bdca-5e90e03b721f' User entered '29 Jan 2021 18:09:47'	System	30 Jan 2021 02:11:21



**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[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 (f638d9a4fd639462)', Time: '2021-02-04T06:57:32', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'a2491b50-d276-4497-a389-5c6ee3441756'	System	04 Feb 2021 14:58:02
User entered 'No (N)'	System	04 Feb 2021 14:58:02

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

Have you been exposed to someone with 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 (f638d9a4fd639462)', Time: '2021-02-04T06:57:38', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'a2491b50-d276-4497-a389-5c6ee3441756'	System	04 Feb 2021 14:58:02
User entered 'No (N)'	System	04 Feb 2021 14:58:02

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2021-02-04T06:57:58', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'a2491b50-d276-4497-a389-5c6ee3441756'	System	04 Feb 2021 14:58:02
User entered '04 Feb 2021 06:57:58'	System	04 Feb 2021 14:58:02

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 22:05:04



**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[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 (f638d9a4fd639462)', Time: '2021-02-11T05:37:02', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '4e932af9-bbad-4c35-b898-f57fb3367093'	System	11 Feb 2021 13:37:38
User entered 'No (N)'	System	11 Feb 2021 13:37:38

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Have you been exposed to someone with 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 (f638d9a4fd639462)', Time: '2021-02-11T05:37:15', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '4e932af9-bbad-4c35-b898-f57fb3367093'	System	11 Feb 2021 13:37:38
User entered 'No (N)'	System	11 Feb 2021 13:37:38

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2021-02-11T05:37:32', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '4e932af9-bbad-4c35-b898-f57fb3367093' User entered '11 Feb 2021 05:37:32'	System	11 Feb 2021 13:37:38
	System	11 Feb 2021 13:37:38

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[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 (f638d9a4fd639462)', Time: '2021-02-19T05:49:34', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'd5498bcc-a714-493e-b128-04f350f12e11'	System	19 Feb 2021 13:50:08
User entered 'No (N)'	System	19 Feb 2021 13:50:08



**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

Have you been exposed to someone with 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 (f638d9a4fd639462)', Time: '2021-02-19T05:49:49', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'd5498bcc-a714-493e-b128-04f350f12e11'	System	19 Feb 2021 13:50:08
User entered 'No (N)'	System	19 Feb 2021 13:50:08

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2021-02-19T05:50:04', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'd5498bcc-a714-493e-b128-04f350f12e11'	System	19 Feb 2021 13:50:08
User entered '19 Feb 2021 05:50:04'	System	19 Feb 2021 13:50:08

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[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 (f638d9a4fd639462)', Time: '2021-02-25T05:37:40-08:00', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '944d5cc1-7a8c-45fc-b953-da9074d2cc39'	System	25 Feb 2021 17:54:48
User entered 'No (N)'	System	25 Feb 2021 17:54:48

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

Have you been exposed to someone with 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 (f638d9a4fd639462)', Time: '2021-02-25T05:37:52-08:00', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '944d5cc1-7a8c-45fc-b953-da9074d2cc39'	System	25 Feb 2021 17:54:48
User entered 'No (N)'	System	25 Feb 2021 17:54:48

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2021-02-25T05:37:59-08:00', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '944d5cc1-7a8c-45fc-b953-da9074d2cc39'	System	25 Feb 2021 17:54:48
User entered '25 Feb 2021 05:37:59'	System	25 Feb 2021 17:54:48



**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[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 (f638d9a4fd639462)', Time: '2021-03-04T05:41:47-08:00', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '0feec871-df25-4a23-80c9-d9cd5fb3704f' User entered 'No (N)'	System	04 Mar 2021 13:42:32
	System	04 Mar 2021 13:42:32

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

Have you been exposed to someone with 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 (f638d9a4fd639462)', Time: '2021-03-04T05:40:52-08:00', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '0feec871-df25-4a23-80c9-d9cd5fb3704f'	System	04 Mar 2021 13:42:32
User entered 'No (N)'	System	04 Mar 2021 13:42:32

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2021-03-04T05:42:26-08:00', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '0feec871-df25-4a23-80c9-d9cd5fb3704f' User entered '04 Mar 2021 05:42:26'	System	04 Mar 2021 13:42:32
	System	04 Mar 2021 13:42:32

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 22:05:04



**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[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 (f638d9a4fd639462)', Time: '2021-03-11T05:47:07-08:00', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '3ce5b01e-ee1b-4c7a-a131-faf03df25e8e'	System	11 Mar 2021 13:47:35
User entered 'No (N)'	System	11 Mar 2021 13:47:35

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

Have you been exposed to someone with 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 (f638d9a4fd639462)', Time: '2021-03-11T05:47:16-08:00', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '3ce5b01e-ee1b-4c7a-a131-faf03df25e8e'	System	11 Mar 2021 13:47:35
User entered 'No (N)'	System	11 Mar 2021 13:47:35

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2021-03-11T05:47:29-08:00', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '3ce5b01e-ee1b-4c7a-a131-faf03df25e8e' User entered '11 Mar 2021 05:47:29'	System	11 Mar 2021 13:47:35
	System	11 Mar 2021 13:47:35

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[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 (f638d9a4fd639462)', Time: '2021-03-20T16:57:58-07:00', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '5b726831-8796-4523-86dd-ffd1e1b8359f'	System	20 Mar 2021 23:58:15
User entered 'No (N)'	System	20 Mar 2021 23:58:15



**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

Have you been exposed to someone with 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 (f638d9a4fd639462)', Time: '2021-03-20T16:58:03-07:00', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '5b726831-8796-4523-86dd-ffd1e1b8359f'	System	20 Mar 2021 23:58:15
User entered 'No (N)'	System	20 Mar 2021 23:58:15

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2021-03-20T16:58:13-07:00', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '5b726831-8796-4523-86dd-ffd1e1b8359f'	System	20 Mar 2021 23:58:15
User entered '20 Mar 2021 16:58:13'	System	20 Mar 2021 23:58:15

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[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 (f638d9a4fd639462)', Time: '2021-03-25T05:34:07-07:00', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '12fc9cdd-3f19-415f-a92e-5529b5a3bc19'	System	25 Mar 2021 12:34:26
User entered 'No (N)'	System	25 Mar 2021 12:34:26

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

Have you been exposed to someone with 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 (f638d9a4fd639462)', Time: '2021-03-25T05:34:10-07:00', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '12fc9cdd-3f19-415f-a92e-5529b5a3bc19'	System	25 Mar 2021 12:34:26
User entered 'No (N)'	System	25 Mar 2021 12:34:26

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2021-03-25T05:34:23-07:00', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '12fc9cdd-3f19-415f-a92e-5529b5a3bc19' User entered '25 Mar 2021 05:34:23'	System	25 Mar 2021 12:34:26
	System	25 Mar 2021 12:34:26



**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[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 (f638d9a4fd639462)', Time: '2021-04-02T09:56:11-07:00', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'e0dcb25d-844a-47cc-a85f-25b922cb1813'	System	02 Apr 2021 16:56:33
User entered 'No (N)'	System	02 Apr 2021 16:56:33

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

Have you been exposed to someone with 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 (f638d9a4fd639462)', Time: '2021-04-02T09:56:16-07:00', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'e0dcb25d-844a-47cc-a85f-25b922cb1813'	System	02 Apr 2021 16:56:33
User entered 'No (N)'	System	02 Apr 2021 16:56:33

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2021-04-02T09:56:27-07:00', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'e0dcb25d-844a-47cc-a85f-25b922cb1813'	System	02 Apr 2021 16:56:33
User entered '02 Apr 2021 09:56:27'	System	02 Apr 2021 16:56:33

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 22:05:04



**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[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 (f638d9a4fd639462)', Time: '2021-04-09T15:17:22-07:00', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'c0f62add-3601-493d-829e-5bd7a75816e5'	System	09 Apr 2021 22:17:41
User entered 'No (N)'	System	09 Apr 2021 22:17:41

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

Have you been exposed to someone with 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 (f638d9a4fd639462)', Time: '2021-04-09T15:17:29-07:00', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'c0f62add-3601-493d-829e-5bd7a75816e5'	System	09 Apr 2021 22:17:41
User entered 'No (N)'	System	09 Apr 2021 22:17:41

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2021-04-09T15:17:37-07:00', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'c0f62add-3601-493d-829e-5bd7a75816e5' User entered '09 Apr 2021 15:17:37'	System	09 Apr 2021 22:17:41
	System	09 Apr 2021 22:17:41

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[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 (f638d9a4fd639462)', Time: '2021-04-15T12:22:03-07:00', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '5269c3d5-d84b-437b-ba5e-4e2b1dffe03'	System	15 Apr 2021 19:22:25
User entered 'No (N)'	System	15 Apr 2021 19:22:25



**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

Have you been exposed to someone with 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 (f638d9a4fd639462)', Time: '2021-04-15T12:22:10-07:00', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '5269c3d5-d84b-437b-ba5e-4e2b1dffef03'	System	15 Apr 2021 19:22:25
User entered 'No (N)'	System	15 Apr 2021 19:22:25

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2021-04-15T12:22:19-07:00', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '5269c3d5-d84b-437b-ba5e-4e2b1dffe03'	System	15 Apr 2021 19:22:25
User entered '15 Apr 2021 12:22:19'	System	15 Apr 2021 19:22:25

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[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 (f638d9a4fd639462)', Time: '2021-04-22T05:38:09-07:00', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'b6c237e3-d68b-4632-bf4b-23a36067b597'	System	22 Apr 2021 12:38:38
User entered 'No (N)'	System	22 Apr 2021 12:38:38

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

Have you been exposed to someone with 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 (f638d9a4fd639462)', Time: '2021-04-22T05:38:21-07:00', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'b6c237e3-d68b-4632-bf4b-23a36067b597'	System	22 Apr 2021 12:38:38
User entered 'No (N)'	System	22 Apr 2021 12:38:38

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2021-04-22T05:38:34-07:00', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'b6c237e3-d68b-4632-bf4b-23a36067b597'	System	22 Apr 2021 12:38:38
User entered '22 Apr 2021 05:38:34'	System	22 Apr 2021 12:38:38



**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[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 (f638d9a4fd639462)', Time: '2021-04-29T06:01:23-07:00', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '199fda42-3bc6-48d8-9100-fc7f675df269'	System	29 Apr 2021 13:02:22
User entered 'No (N)'	System	29 Apr 2021 13:02:22

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

Have you been exposed to someone with 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 (f638d9a4fd639462)', Time: '2021-04-29T06:01:31-07:00', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '199fda42-3bc6-48d8-9100-fc7f675df269'	System	29 Apr 2021 13:02:22
User entered 'No (N)'	System	29 Apr 2021 13:02:22

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2021-04-29T06:01:46-07:00', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: '199fda42-3bc6-48d8-9100-fc7f675df269' User entered '29 Apr 2021 06:01:46'	System	29 Apr 2021 13:02:22
	System	29 Apr 2021 13:02:22

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 22:05:04



**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 22:05:04



**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 22:05:04



**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 22:05:04



**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 22:05:04



**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 22:05:04



**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 22:05:04



**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 22:05:04



**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 22:05:04



**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 22:05:04



**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 22:05:04



**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 22:05:04



**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 22:05:04



**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 22:05:04



**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 22:05:04



**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 22:05:04



**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 22:05:04



**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 22:05:04



**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 22:05:04

**US3732249**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 22:05:04



**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 22:05:04



**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 22:05:04



**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 22:05:04



**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 22:05:04



**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 22:05:04



**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 22:05:04



**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 22:05:04



**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 22:05:04



**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 22:05:04



**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 22:05:04



**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '20 Oct 2022 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '24 Oct 2022 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 22:05:04



**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '27 Oct 2022 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '31 Oct 2022 23:59'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '03 Nov 2022 00:01'	System	19 Nov 2020 22:05:04

**US3732249**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:34:18**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:05:04
Amendment Manager: User entered '07 Nov 2022 23:59'	System	19 Nov 2020 22:05:04

US3732249

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 09:34:18**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:58:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2021-03-04T05:40:18-08:00', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'e08fe986-cf03-4103-a0c8-559e6a666a07'	System	04 Mar 2021 13:40:36
User entered 'No (N)'	System	04 Mar 2021 13:40:36

**US3732249**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:58:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f638d9a4fd639462)', Time: '2021-03-04T05:40:28-08:00', User OID: 'PatientReportedOutcome (US3732249)', ODM File OID: 'e08fe986-cf03-4103-a0c8-559e6a666a07'	System	04 Mar 2021 13:40:36
User entered '04 Mar 2021 05:40:28'	System	04 Mar 2021 13:40:36

**US3732249**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:34:18**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Yes (Y)'	Linda Vega (b) (4)	24 Nov 2020 20:33:10



**US3732249**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:34:18**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '24 Nov 2020'	Linda Vega (b) (4)	24 Nov 2020 20:33:10

**US3732249**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:34:18**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Contact Made (CONTACT MADE)'	Linda Vega (b) (4)	24 Nov 2020 20:33:10

**US3732249**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:34:18**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered empty.	Linda Vega (b) (4)	24 Nov 2020 20:33:10

**US3732249**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:34:18**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Yes (Y)'	Linda Vega (b) (4)	24 Nov 2020 20:33:15

**US3732249**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:34:18**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 08:06:13
User entered 'I'	System	24 Nov 2020 20:33:15

**US3732249**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:34:18**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:33
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Yes (Y)'	(b) (4) Sylvia Lindholm (b) (4)	28 Dec 2020 18:59:58

**US3732249**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:34:18**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:33
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '28 Dec 2020'	(b) (4) Sylvia Lindholm (b) (4)	28 Dec 2020 18:59:58

**US3732249**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:34:18**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:33
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sylvia Lindholm (b) (4)	28 Dec 2020 18:59:58



**US3732249**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:34:18**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:33
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered empty.	(b) (4) Sylvia Lindholm (b) (4)	28 Dec 2020 18:59:58

**US3732249**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:34:18**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:33
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Yes (Y)'	(b) (4) Sylvia Lindholm (b) (4)	28 Dec 2020 19:00:02

**US3732249**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:34:18**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:33
User entered 'I'	System	28 Dec 2020 19:00:02

US3732249

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:34:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:33
User closed query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab(Single): Sample dated 25-Feb-2021 is reported under OL-D1 visit in PPD Central lab, however the same is missing in EDC under Participant Decision Visit OL-D1(1).Please review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 10:39:31
Query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab(Single): Sample dated 25-Feb-2021 is reported under OL-D1 visit in PPD Central lab, however the same is missing in EDC under Participant Decision Visit OL-D1(1).Please review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' answered with 'updated' (Site from DM).	He (Helen) Pu (b) (4) (b) (4)	10 Mar 2021 19:40:24
User opened query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab(Single): Sample dated 25-Feb-2021 is reported under OL-D1 visit in PPD Central lab, however the same is missing in EDC under Participant Decision Visit OL-D1(1).Please review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 05:03:34
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	25 Feb 2021 02:01:08
User entered 'Yes (Y)'	Linda Vega (b) (4) (b) (4)	26 Jan 2021 22:23:45

**US3732249**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:34:18**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:33
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '26 Jan 2021'	Linda Vega (b) (4)	26 Jan 2021 22:23:45

**US3732249**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:34:18**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:33
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Contact Made (CONTACT MADE)'	Linda Vega (b) (4)	26 Jan 2021 22:23:45

**US3732249**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:34:18**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:33
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered empty.	Linda Vega (b) (4)	26 Jan 2021 22:23:45

**US3732249**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:34:18**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:33
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Yes (Y)'	Linda Vega (b) (4)	26 Jan 2021 22:23:52



**US3732249**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:34:18**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:33
User entered 'I'	System	26 Jan 2021 22:23:52

**US3732249**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:34:18**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:59:48
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
	(b) (4)	
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	25 Mar 2021 20:10:03
	(b) (4)	

US3732249

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:34:18

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:59:48
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
	(b) (4)	
User closed query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	25 Mar 2021 20:10:59
Query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	25 Mar 2021 20:10:59
User entered '25 Feb 2021' reason for change: Data Entry Error	Gordon Bovee (b) (4)	25 Mar 2021 20:10:59
	(b) (4)	
User opened query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	25 Mar 2021 20:10:03
User entered '25 Mar 2021'	Gordon Bovee (b) (4)	25 Mar 2021 20:10:03
	(b) (4)	

**US3732249**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:34:18**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	30 Apr 2021 15:59:48
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	09 Apr 2021 21:24:27
User entered 'Contact Made (CONTACT MADE)'	Gordon Bovee (b) (4) (b) (4)	25 Mar 2021 20:10:03

US3732249

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:34:18

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:59:48
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
	(b) (4)	
User entered empty.	Gordon Bovee (b) (4)	25 Mar 2021 20:10:03
	(b) (4)	

US3732249

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:34:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	30 Apr 2021 15:59:48
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	09 Apr 2021 21:24:27
User entered 'Yes (Y)'	Gordon Bovee (b) (4) (b) (4)	25 Mar 2021 20:10:33

**US3732249**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:34:18**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:59:48
User entered 'I'	System	25 Mar 2021 20:10:33

**US3732249**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:34:18**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:20
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
User entered 'Yes (Y)'	(b) (4) Gordon Bovee (b) (4)	25 Mar 2021 20:11:26



**US3732249**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:34:18**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:20
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
User entered '25 Mar 2021'	(b) (4) Gordon Bovee (b) (4)	25 Mar 2021 20:11:26

**US3732249**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:34:18**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:20
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
User entered 'Clinic (Clinic)'	Gordon Bovee (b) (4)	25 Mar 2021 20:11:26

**US3732249**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:34:18**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:20
User entered 'VISIT4'	System	25 Mar 2021 20:11:26

**US3732249**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:20
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
User entered 'Yes (Y)'	(b) (4) Sylvia Lindholm (b) (4)	01 Apr 2021 17:05:49

US3732249

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:34:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:20
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
User entered '25 Mar 2021'	(b) (4) Sylvia Lindholm (b) (4)	01 Apr 2021 17:05:49

**US3732249**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:20
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
User entered '09:33'	(b) (4) Sylvia Lindholm (b) (4)	01 Apr 2021 17:05:49

**US3732249**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:20
User entered '25 Mar 2021 09:33'	System	01 Apr 2021 17:05:49

US3732249

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:34:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:20
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
User entered '97.7' F	(b) (4) Sylvia Lindholm (b) (4)	01 Apr 2021 17:05:49



**US3732249**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:20
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
User entered 'Oral (Oral)'	(b) (4) Sylvia Lindholm (b) (4)	01 Apr 2021 17:05:49

**US3732249**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:20
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
User entered empty.	(b) (4) Sylvia Lindholm (b) (4)	01 Apr 2021 17:05:49

**US3732249**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:20
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
User entered '59'	(b) (4) Sylvia Lindholm (b) (4)	01 Apr 2021 17:05:49

**US3732249**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:20
User entered 'bpm'	System	01 Apr 2021 17:05:49

US3732249

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:34:18

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:20
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
User entered '16'	(b) (4) Sylvia Lindholm (b) (4)	01 Apr 2021 17:05:49

**US3732249**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:20
User entered 'breaths/min'	System	01 Apr 2021 17:05:49

US3732249

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:34:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:20
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
User entered '124'	(b) (4) Sylvia Lindholm (b) (4)	01 Apr 2021 17:05:49

**US3732249**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:20
User entered 'mmHg'	System	01 Apr 2021 17:05:49



US3732249

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:34:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:20
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
User entered '70'	(b) (4) Sylvia Lindholm (b) (4)	01 Apr 2021 17:05:49

**US3732249**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:20
User entered 'mmHg'	System	01 Apr 2021 17:05:49

**US3732249**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	27 Apr 2021 05:41:20

**US3732249**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	27 Apr 2021 05:41:20

**US3732249**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:34:18**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:20
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	25 Mar 2021 20:11:42

**US3732249**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:34:18**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:20
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
User entered '25 Mar 2021'	Gordon Bovee (b) (4)	25 Mar 2021 20:11:42

**US3732249**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:34:18**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:20
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	25 Mar 2021 20:11:59

**US3732249**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:34:18**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:20
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
User entered '25 Mar 2021'	(b) (4) Gordon Bovee (b) (4)	25 Mar 2021 20:11:59



**US3732249**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:34:18**

**Collection time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:20
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
User entered '09:38'	(b) (4) Gordon Bovee (b) (4)	25 Mar 2021 20:11:59

**US3732249**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:34:18**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:20
User entered '25 Mar 2021 09:38'	System	25 Mar 2021 20:11:59

**US3732249**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:34:18**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:20
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	25 Mar 2021 20:12:13

**US3732249**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:34:18**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 05:41:20
User entered 'I'	System	25 Mar 2021 20:12:13

**US3732249**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:34:18**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:22:42
	(b) (4)	
User entered 'Yes (Y)'	Sylvia Lindholm (b) (4)	27 Apr 2021 16:18:52

**US3732249**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:34:18**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:22:42
	(b) (4)	
User entered '27 Apr 2021'	Sylvia Lindholm (b) (4)	27 Apr 2021 16:18:52

**US3732249**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:34:18**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:22:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sylvia Lindholm (b) (4)	27 Apr 2021 16:18:52

**US3732249**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:34:18**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:22:42
User entered empty.	(b) (4)	
	Sylvia Lindholm (b) (4)	27 Apr 2021 16:18:52



**US3732249**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:34:18**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:22:42
	(b) (4)	
User entered 'Yes (Y)'	Sylvia Lindholm (b) (4)	27 Apr 2021 16:18:57

**US3732249**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:34:18**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	27 Apr 2021 16:18:57

US3732249

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:34:18

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:01
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:48:00
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 26Oct2020 is reported under Illness visit day 1 in PPD Central lab, however Covid Diagnostic test is not yet entered in EDC. Please reconcile. Else Clarify ' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Jan 2021 08:57:18
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 26Oct2020 is reported under Illness visit day 1 in PPD Central lab, however Covid Diagnostic test is not yet entered in EDC. Please reconcile. Else Clarify ' answered with 'COVID diagnostic test eCRF updated.' (Site from DM).	(b) (4), (b) (6)	01 Jan 2021 00:37:13
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 26Oct2020 is reported under Illness visit day 1 in PPD Central lab, however Covid Diagnostic test is not yet entered in EDC. Please reconcile. Else Clarify ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 03:47:38
User entered '26 Oct 2020'	(b) (4), (b) (6)	26 Oct 2020 21:14:26

US3732249

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:34:18

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:01
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:48:01
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 28OCT2020 is reported under Illness Visits in PPD Central lab, however the data is missing in EDC. Please review if the sample has been collected then update the details in Saliva collection log under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Jan 2021 06:34:11
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 28OCT2020 is reported under Illness Visits in PPD Central lab, however the data is missing in EDC. Please review if the sample has been collected then update the details in Saliva collection log under appropriate visit. Else clarify, thank you.' answered with 'Saliva collection log updated.' (Site from DM).	(b) (4), (b) (6)	01 Jan 2021 00:37:45
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 28OCT2020 is reported under Illness Visits in PPD Central lab, however the data is missing in EDC. Please review if the sample has been collected then update the details in Saliva collection log under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 09:52:49
User entered '11:30'	(b) (4), (b) (6)	26 Oct 2020 21:14:26

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: COVID-19 Contact**

**Generated On: 10 Jun 2021 09:34:18**

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:01
User entered '26 Oct 2020 11:30'	System	26 Oct 2020 21:14:26

US3732249

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:34:18

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:01
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:22:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:41:49
User closed query 'Per Source, "Type of Contact = Safety Call". Please re-confirm with Source and update contact to Safety Call' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 16:41:48
Query 'Per Source, "Type of Contact = Safety Call". Please re-confirm with Source and update contact to Safety Call' answered by data change (Site from CRA).	System	09 Apr 2021 20:13:33
Signature has been broken.	He (Helen) Pu (b) (4)	09 Apr 2021 20:13:33
User entered 'Safety Call (Safety Call)' reason for change: Data Entry Error	(b) (4) He (Helen) Pu (b) (4)	09 Apr 2021 20:13:33
User opened query 'Per Source, "Type of Contact = Safety Call". Please re-confirm with Source and update contact to Safety Call' (Site from CRA).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 22:47:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 26 OCT 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same is missing in EDC.As per the CCG v 2, please add illness folder using ADD EVENT DROP Down and review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 05:54:14
' (Site from DM).		
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 26 OCT 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same is missing in EDC.As per the CCG v 2, please add illness folder using ADD EVENT DROP Down and review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.	(b) (4), (b) (6)	01 Jan 2021 00:38:18
' answered with 'Updated.' (Site from DM).		

US3732249

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:34:18

[Type of Contact](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 26 OCT 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same is missing in EDC. As per the CCG v 2, please add illness folder using ADD EVENT DROP Down and review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 10:28:45
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	(b) (4), (b) (6)	26 Oct 2020 21:14:26

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: COVID-19 Contact**

**Generated On: 10 Jun 2021 09:34:18**

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:01
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:48:05
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:14:26



US3732249

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:34:18

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Day 5 (Day 5)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06
User entered 'Day 1 (Day 1)'	(b) (4), (b) (6)	26 Oct 2020 21:15:26

US3732249

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:34:18

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:50:11
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '26 Oct 2020'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:15:26

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:15:26

US3732249

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:34:18

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:50:21
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '97'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:15:26

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:34:18**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
User entered '%'	System	26 Oct 2020 21:15:26

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:50:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '98.0' F	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:15:26

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:15:26

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:15:26



**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:15:26

US3732249

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:34:18

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:15:26

US3732249

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:34:18

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:15:26

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:15:26

US3732249

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:34:18

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:15:26

US3732249

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:34:18

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:15:26

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:34:18**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:15:26

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:34:18**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:15:26



**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:15:26

US3732249

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:34:18

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:15:26

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:15:26

US3732249

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:34:18

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:15:26

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:50:28
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:15:26

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:15:26

US3732249

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:34:18

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Day 6 (Day 6)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06
User entered 'Day 2 (Day 2)'	(b) (4), (b) (6)	28 Oct 2020 18:19:09

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:50:36
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '27 Oct 2020'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:19:09



**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:19:09

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:34:18**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:50:52
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '99'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:19:09

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:34:18**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
User entered '%'	System	28 Oct 2020 18:19:09

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Form: Symptom Log (2)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:50:53
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '96.6' F	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:19:09

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**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:19:09

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**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:19:09

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**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:19:09

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**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:19:09



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**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:19:09

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:34:18

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:19:09

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:34:18

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:19:09

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:34:18

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:19:09

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**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:34:18**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:19:09

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**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:34:18**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:19:09

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:19:09

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:34:18

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:19:09



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**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:19:09

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Form: Symptom Log (2)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:19:09

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**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:19:09

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**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	28 Oct 2020 18:19:09

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Day 7 (Day 7)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

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**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:34:18**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:02
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '28 Oct 2020'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

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**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:34:18**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:10
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '99'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06



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**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:34:18**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
User entered '%'	System	01 Jan 2021 00:15:06

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Form: Symptom Log (3)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:11
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '96.1' F	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:34:18**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

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Form: Symptom Log (3)

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:34:18

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:34:18

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:34:18

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

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**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:34:18**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06



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Form: Symptom Log (3)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:34:18**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:34:18**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

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**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:34:18**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

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**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (3)**

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

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Form: Symptom Log (3)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

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Form: Symptom Log (3)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06



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**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 09:34:18**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

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Form: Symptom Log (3)

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[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

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Form: Symptom Log (4)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Day 1 (Day 1)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:34:18**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:48:53
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '22 Oct 2020'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

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**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:34:18**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User closed query 'Per CDM: it appears that both O2 Saturation and Temperature were not collected for Days 1 - 4. If not collected please consider recording this as Not Done. Thankyou.' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 16:24:14
Query 'Per CDM: it appears that both O2 Saturation and Temperature were not collected for Days 1 - 4. If not collected please consider recording this as Not Done. Thankyou.' answered with 'Updated per request.' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 20:09:03
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4), (b) (6)	03 Feb 2021 20:07:14
User opened query 'Per CDM: it appears that both O2 Saturation and Temperature were not collected for Days 1 - 4. If not collected please consider recording this as Not Done. Thankyou.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 13:08:57
User entered empty.	(b) (4), (b) (6)	01 Jan 2021 00:15:06

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Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:34:18

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
User entered '%'	System	03 Feb 2021 20:07:14
User entered empty.	System	01 Jan 2021 00:15:06

US3732249

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:34:18

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered missing code ND - Not Done; reason for	(b) (4)	
change Per Query Resolution	(b) (4), (b) (6)	03 Feb 2021 20:07:14
User entered empty.	(b) (4), (b) (6)	01 Jan 2021 00:15:06



**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:34:18**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:34:18**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:34:18**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

US3732249

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:34:18

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

US3732249

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:34:18

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:34:18**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

US3732249

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:34:18

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

US3732249

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:34:18

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06



**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:34:18**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:34:18

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:34:18**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:34:18**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 09:34:18**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:34:18

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:34:18

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:48:56
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:34:18

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06



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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:34:18

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Day 2 (Day 2)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:34:18**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:49:13
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:34:18**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '0'	(b) (4), (b) (6)	01 Jan 2021 00:15:06

US3732249

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:34:18

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered missing code ND - Not Done; reason for	(b) (4)	
change Per Query Resolution	(b) (4), (b) (6)	03 Feb 2021 20:07:36
User entered empty.	(b) (4), (b) (6)	01 Jan 2021 00:15:06

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:34:18

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
User entered '%'	System	03 Feb 2021 20:07:36
User entered empty.	System	01 Jan 2021 00:15:06

US3732249

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:34:18

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered missing code ND - Not Done; reason for	(b) (4)	
change Per Query Resolution	(b) (4), (b) (6)	03 Feb 2021 20:07:36
User entered empty.	(b) (4), (b) (6)	01 Jan 2021 00:15:06

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:34:18**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:34:18

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06



**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:34:18**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:34:18**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:34:18**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:34:18**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:34:18**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:34:18

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:34:18**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:34:18**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06



**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:34:18**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

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**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:34:18**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:34:18**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:34:18**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 09:34:18**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:49:23
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:34:18

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:34:18

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Day 3 (Day 3)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:34:18**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:49:31
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '24 Oct 2020'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06



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**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:34:18**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '0'	(b) (4), (b) (6)	01 Jan 2021 00:15:06

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:34:18

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered missing code ND - Not Done; reason for	(b) (4)	
change Per Query Resolution	(b) (4), (b) (6)	03 Feb 2021 20:07:50
User entered empty.	(b) (4), (b) (6)	01 Jan 2021 00:15:06

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:34:18

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
User entered '%'	System	03 Feb 2021 20:07:50
User entered empty.	System	01 Jan 2021 00:15:06

US3732249

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:34:18

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered missing code ND - Not Done; reason for	(b) (4)	
change Per Query Resolution	(b) (4), (b) (6)	03 Feb 2021 20:07:50
User entered empty.	(b) (4), (b) (6)	01 Jan 2021 00:15:06

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:34:18**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:34:18**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:34:18

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:34:18**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06



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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:34:18

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:34:18**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:34:18**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:34:18

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:34:18**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:34:18**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:34:18**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:34:18**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06



**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:34:18**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:34:18**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:34:18**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:49:35
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 09:34:18**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

US3732249

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:34:18

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Day 4 (Day 4)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:34:18**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:49:44
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '25 Oct 2020'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:34:18**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '0'	(b) (4), (b) (6)	01 Jan 2021 00:15:06

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:34:18**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered missing code ND - Not Done; reason for	(b) (4)	
change Per Query Resolution	(b) (4), (b) (6)	03 Feb 2021 20:08:04
User entered empty.	(b) (4), (b) (6)	01 Jan 2021 00:15:06



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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
User entered '%'	System	03 Feb 2021 20:08:04
User entered empty.	System	01 Jan 2021 00:15:06

US3732249

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:34:18

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered missing code ND - Not Done; reason for	(b) (4)	
change Per Query Resolution	(b) (4), (b) (6)	03 Feb 2021 20:08:04
User entered empty.	(b) (4), (b) (6)	01 Jan 2021 00:15:06

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:34:18**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:34:18**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:34:18**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:34:18**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:34:18**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:34:18**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06



**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:34:18**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:34:18

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:34:18**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:34:18**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:34:18**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

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**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:34:18**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:34:18**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:34:18

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06



**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 09:34:18**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:49:58
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

US3732249

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:34:18

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:14
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:51:49
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:15:06

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: COVID Diagnostic Test**

**Generated On: 10 Jun 2021 09:34:18**

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:24
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:52:04
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '26 Oct 2020'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:16:24

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: COVID Diagnostic Test**

**Generated On: 10 Jun 2021 09:34:18**

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:24
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:52:04
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:16:24

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: COVID Diagnostic Test**

**Generated On: 10 Jun 2021 09:34:18**

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:24
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:52:04
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:16:24

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: COVID Diagnostic Test**

**Generated On: 10 Jun 2021 09:34:18**

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:24
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:52:04
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '26 Oct 2020'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:16:24

US3732249

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:34:18

Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:24
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:52:04
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4), (b) (6)	01 Jan 2021 00:16:24

US3732249

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:34:18

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:24
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:52:04
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered empty.	(b) (4), (b) (6)	01 Jan 2021 00:16:24



US3732249

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:34:18

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:24
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:52:04
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:16:24

US3732249

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:34:18

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:24
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:52:04
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:16:24

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: COVID Diagnostic Test**

**Generated On: 10 Jun 2021 09:34:18**

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:24
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:52:04
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:16:24

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: COVID Diagnostic Test**

**Generated On: 10 Jun 2021 09:34:18**

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:24
User entered '0'	System	01 Jan 2021 00:16:24

**US3732249**

**Folder: Covid-19 Assessment 26 Oct 2020**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 10 Jun 2021 09:34:18**

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 19:27:31
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:52:31
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Jan 2021 23:54:06

**US3732249**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:16:18
User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	01 Jan 2021 00:29:45

**US3732249**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:16:18
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:53:44
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Jan 2021 00:29:45

**US3732249**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:16:18
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:53:44
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '28 Oct 2020'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:29:45



**US3732249**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:16:18
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	01 Jan 2021 00:29:45

**US3732249**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:16:18
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:53:44
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:29:45

**US3732249**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:16:18
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:53:44
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered empty.	(b) (4), (b) (6)	01 Jan 2021 00:29:45

**US3732249**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 10 Jun 2021 09:34:18**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:16:18
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	01 Jan 2021 00:29:45

**US3732249**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 10 Jun 2021 09:34:18**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:16:18
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:53:44
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4), (b) (6)	01 Jan 2021 00:29:45

**US3732249**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 10 Jun 2021 09:34:18**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:16:18
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:53:44
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered empty.	(b) (4), (b) (6)	01 Jan 2021 00:29:45

**US3732249**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 10 Jun 2021 09:34:18**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:16:18
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	01 Jan 2021 00:29:45

**US3732249**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 10 Jun 2021 09:34:18**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:16:18
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:53:44
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:29:45



**US3732249**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 10 Jun 2021 09:34:18**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:16:18
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:53:44
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered empty.	(b) (4), (b) (6)	01 Jan 2021 00:29:45

**US3732249**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 10 Jun 2021 09:34:18**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:16:18
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	01 Jan 2021 00:29:45

**US3732249**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 10 Jun 2021 09:34:18**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:16:18
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:53:44
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:29:45

**US3732249**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 10 Jun 2021 09:34:18**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:16:18
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:53:44
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered empty.	(b) (4), (b) (6)	01 Jan 2021 00:29:45

**US3732249**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 10 Jun 2021 09:34:18**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:16:18
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	01 Jan 2021 00:29:45

**US3732249**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 10 Jun 2021 09:34:18**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:16:18
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:53:44
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:29:45

**US3732249**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 10 Jun 2021 09:34:18**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:16:18
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:53:44
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered empty.	(b) (4), (b) (6)	01 Jan 2021 00:29:45

**US3732249**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 10 Jun 2021 09:34:18**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:16:18
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	01 Jan 2021 00:29:45



**US3732249**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 10 Jun 2021 09:34:18**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:16:18
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:53:44
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:29:45

**US3732249**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 10 Jun 2021 09:34:18**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:16:18
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:53:44
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered empty.	(b) (4), (b) (6)	01 Jan 2021 00:29:45

**US3732249**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:34:18**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:16:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:52:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:22:08

**US3732249**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:34:18**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:16:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:52:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '26 Oct 2020'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:22:08

**US3732249**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:34:18**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:16:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:52:41
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:22:08

**US3732249**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:34:18**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:16:54
User entered 'SICKD1'	System	01 Jan 2021 00:22:08

**US3732249**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:16:47
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:53:05
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:26:12

**US3732249**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:16:47
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:53:05
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '26 Oct 2020'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:26:12



**US3732249**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:16:47
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:53:05
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '13:10'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:26:12

**US3732249**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:16:47
User entered '26 Oct 2020 13:10'	System	01 Jan 2021 00:26:12

**US3732249**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:16:47
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:53:05
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '177.0' cm	(b) (4), (b) (6)	01 Jan 2021 00:26:12
DataPoint set to visible.	System	01 Jan 2021 00:22:08

**US3732249**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:16:47
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:53:05
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '77.5' kg	(b) (4), (b) (6)	01 Jan 2021 00:26:12
DataPoint set to visible.	System	01 Jan 2021 00:22:08

**US3732249**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:16:47
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:53:05
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '98.0' F	(b) (4), (b) (6)	01 Jan 2021 00:26:12

**US3732249**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:16:47
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:53:05
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:26:12

**US3732249**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:16:47
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:53:05
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered empty.	(b) (4), (b) (6)	01 Jan 2021 00:26:12

**US3732249**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:16:47
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:53:05
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '60'	(b) (4), (b) (6)	01 Jan 2021 00:26:12



**US3732249**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:16:47
User entered 'bpm'	System	01 Jan 2021 00:26:12

**US3732249**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:16:47
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:53:05
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '16'	(b) (4), (b) (6)	01 Jan 2021 00:26:12

**US3732249**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:16:47
User entered 'breaths/min'	System	01 Jan 2021 00:26:12

**US3732249**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:16:47
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:53:05
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '135'	(b) (4), (b) (6)	01 Jan 2021 00:26:12

**US3732249**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:16:47
User entered 'mmHg'	System	01 Jan 2021 00:26:12

**US3732249**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:16:47
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:53:05
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '69'	(b) (4), (b) (6)	01 Jan 2021 00:26:12

**US3732249**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:16:47
User entered 'mmHg'	System	01 Jan 2021 00:26:12

**US3732249**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:16:47



**US3732249**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:16:47

**US3732249**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:34:18**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:16:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:53:12
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Jan 2021 00:22:29

**US3732249**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:34:18**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:16:37
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:53:12
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '26 Oct 2020'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:22:29

US3732249

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 09:34:18

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:16:29
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:53:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:22:54

**US3732249**

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 10 Jun 2021 09:34:18**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:16:29
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:53:19
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '26 Oct 2020'	(b) (4) (b) (4), (b) (6)	01 Jan 2021 00:22:54

**US3732249**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:34:18**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
	(b) (4)	
User entered 'Yes (Y)'	He (Helen) Pu (b) (4)	10 Mar 2021 19:31:27
	(b) (4)	

**US3732249**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:34:18**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
	(b) (4)	
User entered '25 Feb 2021'	He (Helen) Pu (b) (4)	10 Mar 2021 19:31:27
	(b) (4)	

**US3732249**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:34:18**

[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 20:51:31
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
	(b) (4)	
User entered 'Clinic (Clinic)'	He (Helen) Pu (b) (4)	10 Mar 2021 19:31:27
	(b) (4)	



**US3732249**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:34:18**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User entered 'UNBLND_DECIDE'	System	10 Mar 2021 19:31:27

US3732249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:34:18

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
	(b) (4)	
User entered '25 Feb 2021'	He (Helen) Pu (b) (4)	10 Mar 2021 19:33:33
	(b) (4)	

**US3732249**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:34:18**

[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 20:51:31
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
	(b) (4)	
User entered '0'	He (Helen) Pu (b) (4)	10 Mar 2021 19:33:33
	(b) (4)	

**US3732249**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:34:18**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
	(b) (4)	
User entered 'Yes (Y)'	He (Helen) Pu (b) (4)	10 Mar 2021 19:33:33
	(b) (4)	

**US3732249**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:34:18**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
	(b) (4)	
User entered 'Amendment 6 or later (Amendment 6 or later)'	He (Helen) Pu (b) (4)	10 Mar 2021 19:33:33
	(b) (4)	

US3732249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:34:18

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
	(b) (4)	
User entered '25 Feb 2021'	He (Helen) Pu (b) (4)	10 Mar 2021 19:33:33
	(b) (4)	

US3732249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:34:18

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
	(b) (4)	
User entered 'Placebo (Placebo)'	He (Helen) Pu (b) (4)	10 Mar 2021 19:33:33
	(b) (4)	

**US3732249**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:34:18**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
	(b) (4)	
User entered 'Placebo (Placebo)'	He (Helen) Pu (b) (4)	10 Mar 2021 19:33:33
	(b) (4)	



**US3732249**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:34:18**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
	(b) (4)	
User entered 'Placebo (Placebo)'	He (Helen) Pu (b) (4)	10 Mar 2021 19:33:33
	(b) (4)	

US3732249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:34:18

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
	(b) (4)	
User entered 'Yes (Y)'	He (Helen) Pu (b) (4)	10 Mar 2021 19:33:33
	(b) (4)	

**US3732249**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:34:18**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User entered 'I'	System	10 Mar 2021 19:33:33

**US3732249**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:34:18**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User entered 'I'	System	10 Mar 2021 19:33:33

US3732249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:34:18

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	He (Helen) Pu (b) (4)	10 Mar 2021 19:36:05
	(b) (4)	
User entered empty.	He (Helen) Pu (b) (4)	10 Mar 2021 19:35:54
	(b) (4)	

US3732249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:34:18

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	He (Helen) Pu (b) (4)	10 Mar 2021 19:36:05
	(b) (4)	
User entered empty.	He (Helen) Pu (b) (4)	10 Mar 2021 19:35:54
	(b) (4)	

**US3732249**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:34:18**

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User entered empty.	System	10 Mar 2021 19:35:54
DataPoint set to visible.	System	10 Mar 2021 19:33:33

US3732249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:34:18

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	He (Helen) Pu (b) (4)	10 Mar 2021 19:36:05
	(b) (4)	
User entered empty.	He (Helen) Pu (b) (4)	10 Mar 2021 19:35:54
	(b) (4)	



US3732249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:34:18

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	He (Helen) Pu (b) (4)	10 Mar 2021 19:36:05
	(b) (4)	
User entered empty.	He (Helen) Pu (b) (4)	10 Mar 2021 19:35:54
	(b) (4)	

US3732249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:34:18

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User entered empty.	System	10 Mar 2021 19:35:54
DataPoint set to visible.	System	10 Mar 2021 19:33:33

US3732249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:34:18

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User accepted default value 'Pre-Dose (PREDOSE)'	He (Helen) Pu (b) (4)	10 Mar 2021 19:35:54
	(b) (4)	

US3732249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:34:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
	(b) (4)	
User entered 'Yes (Y)'	He (Helen) Pu (b) (4)	10 Mar 2021 19:35:54
	(b) (4)	

US3732249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:34:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
	(b) (4)	
User entered '25 Feb 2021'	He (Helen) Pu (b) (4)	10 Mar 2021 19:35:54
	(b) (4)	

**US3732249**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
	(b) (4)	
User entered '16:04'	He (Helen) Pu (b) (4)	10 Mar 2021 19:35:54
	(b) (4)	

**US3732249**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User entered '25 Feb 2021 16:04'	System	10 Mar 2021 19:35:54

US3732249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:34:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
	(b) (4)	
User entered '97.6' F	He (Helen) Pu (b) (4)	10 Mar 2021 19:35:54
	(b) (4)	



US3732249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:34:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
	(b) (4)	
User entered 'Oral (Oral)'	He (Helen) Pu (b) (4)	10 Mar 2021 19:35:54
	(b) (4)	

**US3732249**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:34:18**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
	(b) (4)	
User entered empty.	He (Helen) Pu (b) (4)	10 Mar 2021 19:35:54
	(b) (4)	

**US3732249**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
	(b) (4)	
User entered '58'	He (Helen) Pu (b) (4)	10 Mar 2021 19:35:54
	(b) (4)	

**US3732249**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User entered 'bpm'	System	10 Mar 2021 19:35:54

US3732249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:34:18

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
	(b) (4)	
User entered '16'	He (Helen) Pu (b) (4)	10 Mar 2021 19:35:54
	(b) (4)	

US3732249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:34:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User entered 'breaths/min'	System	10 Mar 2021 19:35:54

US3732249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:34:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
	(b) (4)	
User entered '105'	He (Helen) Pu (b) (4)	10 Mar 2021 19:35:54
	(b) (4)	

**US3732249**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User entered 'mmHg'	System	10 Mar 2021 19:35:54



US3732249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:34:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	10 Mar 2021 20:28:45
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS per investigator' (Site from System).	He (Helen) Pu (b) (4)	10 Mar 2021 19:36:27
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4)	10 Mar 2021 19:35:54
User entered '52'	He (Helen) Pu (b) (4)	10 Mar 2021 19:35:54

**US3732249**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User entered 'mmHg'	System	10 Mar 2021 19:35:54

US3732249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:34:18

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	He (Helen) Pu (b) (4)	10 Mar 2021 19:36:05
	(b) (4)	
User entered empty.	He (Helen) Pu (b) (4)	10 Mar 2021 19:35:54
	(b) (4)	

US3732249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:34:18

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	He (Helen) Pu (b) (4)	10 Mar 2021 19:36:05
	(b) (4)	
User entered empty.	He (Helen) Pu (b) (4)	10 Mar 2021 19:35:54
	(b) (4)	

US3732249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:34:18

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User entered empty.	System	10 Mar 2021 19:35:54
DataPoint set to visible.	System	10 Mar 2021 19:33:33

US3732249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:34:18

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User accepted default value 'Post-Dose (POSTDOSE)'	He (Helen) Pu (b) (4)	10 Mar 2021 19:35:54
	(b) (4)	

US3732249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:34:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
	(b) (4)	
User entered 'Yes (Y)'	He (Helen) Pu (b) (4)	10 Mar 2021 19:35:54
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:34:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
	(b) (4)	
User entered '25 Feb 2021'	He (Helen) Pu (b) (4)	10 Mar 2021 19:35:54
	(b) (4)	



**US3732249**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
	(b) (4)	
User entered '16:59'	He (Helen) Pu (b) (4)	10 Mar 2021 19:35:54
	(b) (4)	

**US3732249**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User entered '25 Feb 2021 16:59'	System	10 Mar 2021 19:35:54

US3732249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:34:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
	(b) (4)	
User entered '97.6' F	He (Helen) Pu (b) (4)	10 Mar 2021 19:35:54
	(b) (4)	

**US3732249**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
	(b) (4)	
User entered 'Oral (Oral)'	He (Helen) Pu (b) (4)	10 Mar 2021 19:35:54
	(b) (4)	

US3732249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:34:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
	(b) (4)	
User entered empty.	He (Helen) Pu (b) (4)	10 Mar 2021 19:35:54
	(b) (4)	

**US3732249**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
	(b) (4)	
User entered '58'	He (Helen) Pu (b) (4)	10 Mar 2021 19:35:54
	(b) (4)	

**US3732249**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User entered 'bpm'	System	10 Mar 2021 19:35:54

US3732249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:34:18

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
	(b) (4)	
User entered '16'	He (Helen) Pu (b) (4)	10 Mar 2021 19:35:54
	(b) (4)	



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:34:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User entered 'breaths/min'	System	10 Mar 2021 19:35:54

US3732249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:34:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
	(b) (4)	
User entered '137'	He (Helen) Pu (b) (4)	10 Mar 2021 19:35:54
	(b) (4)	

US3732249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:34:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User entered 'mmHg'	System	10 Mar 2021 19:35:54

US3732249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:34:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
	(b) (4)	
User entered '72'	He (Helen) Pu (b) (4)	10 Mar 2021 19:35:54
	(b) (4)	

**US3732249**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User entered 'mmHg'	System	10 Mar 2021 19:35:54

US3732249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:34:18

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
	(b) (4)	
User entered 'Yes (Y)'	He (Helen) Pu (b) (4)	10 Mar 2021 19:33:52
	(b) (4)	

**US3732249**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:34:18**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
	(b) (4)	
User entered '25 Feb 2021'	He (Helen) Pu (b) (4)	10 Mar 2021 19:33:52
	(b) (4)	

US3732249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:34:18

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
	(b) (4)	
User entered 'Yes (Y)'	He (Helen) Pu (b) (4)	10 Mar 2021 19:39:12
	(b) (4)	



US3732249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:34:18

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
	(b) (4)	
User entered empty.	He (Helen) Pu (b) (4)	10 Mar 2021 19:39:12
	(b) (4)	

US3732249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:34:18

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 20:51:31
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
	(b) (4)	
User entered empty.	He (Helen) Pu (b) (4)	10 Mar 2021 19:39:12
	(b) (4)	

**US3732249**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:34:18**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User entered 'mRNA-1273'	System	10 Mar 2021 19:39:12
DataPoint set to visible.	System	10 Mar 2021 19:33:33

US3732249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:34:18

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
	(b) (4)	
User entered '25 Feb 2021'	He (Helen) Pu (b) (4)	10 Mar 2021 19:39:12
	(b) (4)	

US3732249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:34:18

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
	(b) (4)	
User entered '16:26'	He (Helen) Pu (b) (4)	10 Mar 2021 19:39:12
	(b) (4)	

**US3732249**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:34:18**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User entered '25 Feb 2021 16:26'	System	10 Mar 2021 19:39:12

US3732249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:34:18

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	He (Helen) Pu (b) (4)	10 Mar 2021 19:39:12
	(b) (4)	

**US3732249**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:34:18**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User entered 'ONCE'	System	10 Mar 2021 19:39:12



US3732249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:34:18

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User entered 'INTRAMUSCULAR'	System	10 Mar 2021 19:39:12

US3732249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:34:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
	(b) (4)	
User entered 'Yes (Y)'	He (Helen) Pu (b) (4)	10 Mar 2021 19:36:49
	(b) (4)	

US3732249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:34:18

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
	(b) (4)	
User entered '25 Feb 2021'	He (Helen) Pu (b) (4)	10 Mar 2021 19:36:49
	(b) (4)	

**US3732249**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:34:18**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
	(b) (4)	
User entered '15:32'	He (Helen) Pu (b) (4)	10 Mar 2021 19:36:49
	(b) (4)	

**US3732249**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:34:18**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User entered '25 Feb 2021 15:32'	System	10 Mar 2021 19:36:49

**US3732249**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:34:18**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
	(b) (4)	
User entered 'Yes (Y)'	He (Helen) Pu (b) (4)	10 Mar 2021 19:38:37
	(b) (4)	

**US3732249**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:34:18**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
	(b) (4)	
User entered '25 Feb 2021'	He (Helen) Pu (b) (4)	10 Mar 2021 19:38:37
	(b) (4)	

**US3732249**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:34:18**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
	(b) (4)	
User entered '15:27'	He (Helen) Pu (b) (4)	10 Mar 2021 19:38:37
	(b) (4)	



**US3732249**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:34:18**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User entered '25 Feb 2021 15:27'	System	10 Mar 2021 19:38:37

US3732249

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:34:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
	(b) (4)	
User entered 'Yes (Y)'	He (Helen) Pu (b) (4)	10 Mar 2021 19:39:18
	(b) (4)	

**US3732249**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:34:18**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:51:31
User entered '1'	System	10 Mar 2021 19:39:18

**US3732249**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:34:18**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:35:15
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
User entered 'Yes (Y)'	He (Helen) Pu (b) (4)	10 Mar 2021 19:39:37

**US3732249**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:34:18**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:35:15
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
User entered '04 Mar 2021'	He (Helen) Pu (b) (4)	10 Mar 2021 19:39:37

**US3732249**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:34:18**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:35:15
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
User entered 'Contact Made (CONTACT MADE)'	He (Helen) Pu (b) (4)	10 Mar 2021 19:39:37

**US3732249**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:34:18**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:35:15
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
User entered empty.	(b) (4) He (Helen) Pu (b) (4)	10 Mar 2021 19:39:37

**US3732249**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:34:18**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:35:15
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
User entered 'Yes (Y)'	He (Helen) Pu (b) (4)	10 Mar 2021 19:39:53



**US3732249**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:34:18**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:35:15
User entered 'I'	System	10 Mar 2021 19:39:53

**US3732249**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:34:18**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:35:15
User entered 'I'	System	10 Mar 2021 19:39:53
DataPoint set to visible.	System	10 Mar 2021 19:39:53

**US3732249**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:34:18**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:30:38
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
User entered 'Yes (Y)'	Amara Yilmaz (b) (4)	25 Mar 2021 17:02:34

**US3732249**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:34:18**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:30:38
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
User entered '25 Mar 2021'	Amara Yilmaz (b) (4)	25 Mar 2021 17:02:34

**US3732249**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:34:18**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:30:38
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
User entered 'Clinic (Clinic)'	(b) (4) Amara Yilmaz (b) (4) (b) (4)	25 Mar 2021 17:02:34

**US3732249**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:34:18**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:30:38
User entered 'OLD29'	System	25 Mar 2021 17:02:34

**US3732249**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:30:38
User accepted default value 'Pre-Dose (PREDOSE)'	Gordon Bovee (b) (4) (b) (4)	25 Mar 2021 20:21:24

**US3732249**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:30:38
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	25 Mar 2021 20:21:24



**US3732249**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:34:18**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:30:38
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
User entered '25 Mar 2021'	Gordon Bovee (b) (4)	25 Mar 2021 20:21:24

**US3732249**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:34:18**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:30:38
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
User entered '09:33'	(b) (4) Gordon Bovee (b) (4) (b) (4)	25 Mar 2021 20:21:24

**US3732249**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:30:38
User entered '25 Mar 2021 09:33'	System	25 Mar 2021 20:21:24

**US3732249**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:30:38
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
User entered '97.7' F	Gordon Bovee (b) (4)	25 Mar 2021 20:21:24

**US3732249**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:30:38
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
User entered 'Oral (Oral)'	(b) (4) Gordon Bovee (b) (4)	25 Mar 2021 20:21:24

**US3732249**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:34:18**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:30:38
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
User entered empty.	Gordon Bovee (b) (4)	25 Mar 2021 20:21:24

**US3732249**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:30:38
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
User entered '59'	Gordon Bovee (b) (4)	25 Mar 2021 20:21:24

**US3732249**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:30:38
User entered 'bpm'	System	25 Mar 2021 20:21:24



**US3732249**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:30:38
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
User entered '16'	Gordon Bovee (b) (4)	25 Mar 2021 20:21:24

**US3732249**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:30:38
User entered 'breaths/min'	System	25 Mar 2021 20:21:24

**US3732249**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:30:38
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
User entered '124'	Gordon Bovee (b) (4)	25 Mar 2021 20:21:24

**US3732249**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:30:38
User entered 'mmHg'	System	25 Mar 2021 20:21:24

**US3732249**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:30:38
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
User entered '70'	Gordon Bovee (b) (4)	25 Mar 2021 20:21:24

**US3732249**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:30:38
User entered 'mmHg'	System	25 Mar 2021 20:21:24

**US3732249**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:30:38
User accepted default value 'Post-Dose (POSTDOSE)'	Gordon Bovee (b) (4) (b) (4)	25 Mar 2021 20:21:24

**US3732249**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:30:38
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
User entered 'Yes (Y)'	(b) (4) Gordon Bovee (b) (4)	25 Mar 2021 20:21:24



**US3732249**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:34:18**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:30:38
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
User entered '25 Mar 2021'	Gordon Bovee (b) (4)	25 Mar 2021 20:21:24

**US3732249**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:34:18**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:30:38
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
User entered '10:34'	(b) (4) Gordon Bovee (b) (4) (b) (4)	25 Mar 2021 20:21:24

**US3732249**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:30:38
User entered '25 Mar 2021 10:34'	System	25 Mar 2021 20:21:24

**US3732249**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:30:38
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
User entered '98' F	Gordon Bovee (b) (4)	25 Mar 2021 20:21:24

**US3732249**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:30:38
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
User entered 'Oral (Oral)'	(b) (4) Gordon Bovee (b) (4)	25 Mar 2021 20:21:24

**US3732249**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:34:18**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:30:38
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
User entered empty.	(b) (4) Gordon Bovee (b) (4)	25 Mar 2021 20:21:24

**US3732249**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:30:38
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
User entered '53'	Gordon Bovee (b) (4)	25 Mar 2021 20:21:24

**US3732249**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:30:38
User entered 'bpm'	System	25 Mar 2021 20:21:24



**US3732249**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:30:38
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
User entered '15'	Gordon Bovee (b) (4)	25 Mar 2021 20:21:24

**US3732249**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:30:38
User entered 'breaths/min'	System	25 Mar 2021 20:21:24

**US3732249**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:30:38
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
User entered '131'	(b) (4) Gordon Bovee (b) (4)	25 Mar 2021 20:21:24

**US3732249**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:30:38
User entered 'mmHg'	System	25 Mar 2021 20:21:24

US3732249

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:34:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:30:38
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 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)	26 Mar 2021 17:49:47
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Gordon Bovee (b) (4) (b) (4)	25 Mar 2021 20:26:28
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		25 Mar 2021 20:21:24
User entered '56'	Gordon Bovee (b) (4) (b) (4)	25 Mar 2021 20:21:24

**US3732249**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:30:38
User entered 'mmHg'	System	25 Mar 2021 20:21:24

**US3732249**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:34:18**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:30:38
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	25 Mar 2021 20:18:28

**US3732249**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:34:18**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:30:38
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
User entered '25 Mar 2021'	Gordon Bovee (b) (4)	25 Mar 2021 20:18:28



**US3732249**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:34:18**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:30:38
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
User entered 'Yes (Y)'	(b) (4) Amara Yilmaz (b) (4)	25 Mar 2021 17:02:04
	(b) (4)	

**US3732249**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:34:18**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:30:38
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
User entered empty.	(b) (4) Amara Yilmaz (b) (4)	25 Mar 2021 17:02:04

US3732249

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:34:18

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)	01 May 2021 00:30:38
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
User entered empty.	Amara Yilmaz (b) (4)	25 Mar 2021 17:02:04

**US3732249**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:34:18**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:30:38
User entered 'mRNA-1273'	System	25 Mar 2021 17:02:04
DataPoint set to visible.	System	10 Mar 2021 19:39:53

US3732249

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:34:18

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:30:38
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
User entered '25 Mar 2021'	Amara Yilmaz (b) (4)	25 Mar 2021 17:02:04

**US3732249**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:34:18**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:30:38
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
User entered '09:59'	(b) (4) Amara Yilmaz (b) (4)	25 Mar 2021 17:02:04

**US3732249**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:34:18**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:30:38
User entered '25 Mar 2021 09:59'	System	25 Mar 2021 17:02:04

US3732249

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:34:18

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:30:38
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
User entered 'Left Arm (LEFT ARM)'	Amara Yilmaz (b) (4)	25 Mar 2021 17:02:04



US3732249

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:34:18

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:30:38
User entered 'ONCE'	System	25 Mar 2021 17:02:04

**US3732249**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:34:18**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:30:38
User entered 'INTRAMUSCULAR'	System	25 Mar 2021 17:02:04

**US3732249**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:34:18**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:30:38
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	25 Mar 2021 20:26:53

**US3732249**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:34:18**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:30:38
User entered 'I'	System	25 Mar 2021 20:26:53

**US3732249**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:34:18**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
	(b) (4)	
User entered 'Yes (Y)'	Sylvia Lindholm (b) (4)	01 Apr 2021 17:19:20

**US3732249**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:34:18**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
	(b) (4)	
User entered '01 Apr 2021'	Sylvia Lindholm (b) (4)	01 Apr 2021 17:19:20

**US3732249**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:34:18**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sylvia Lindholm (b) (4)	01 Apr 2021 17:19:20

**US3732249**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:34:18**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
User entered empty.	(b) (4) Sylvia Lindholm (b) (4)	01 Apr 2021 17:19:20



**US3732249**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:34:18**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
	(b) (4)	
User entered 'Yes (Y)'	Sylvia Lindholm (b) (4)	01 Apr 2021 17:19:27

**US3732249**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:34:18**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Apr 2021 17:19:27

**US3732249**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:34:18**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:22:42
	(b) (4)	
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	22 Apr 2021 18:00:30
	(b) (4)	

**US3732249**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:34:18**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:22:42
	(b) (4)	
User entered '22 Apr 2021'	Gordon Bovee (b) (4)	22 Apr 2021 18:00:30
	(b) (4)	

**US3732249**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:34:18**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:22:42
	(b) (4)	
User entered 'Clinic (Clinic)'	Gordon Bovee (b) (4)	22 Apr 2021 18:00:30
	(b) (4)	

**US3732249**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:34:18**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	22 Apr 2021 18:00:30

**US3732249**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:22:42
	(b) (4)	
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	22 Apr 2021 18:02:59
	(b) (4)	

**US3732249**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:22:42
	(b) (4)	
User entered '22 Apr 2021'	Gordon Bovee (b) (4)	22 Apr 2021 18:02:59
	(b) (4)	



**US3732249**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:22:42
	(b) (4)	
User entered '10:10'	Gordon Bovee (b) (4)	22 Apr 2021 18:02:59
	(b) (4)	

**US3732249**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '22 Apr 2021 10:10'	System	22 Apr 2021 18:02:59

**US3732249**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

**Temperature (xxx.x)**

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:22:42
	(b) (4)	
User entered '97.8' F	Gordon Bovee (b) (4)	22 Apr 2021 18:02:59
	(b) (4)	

**US3732249**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:22:42
	(b) (4)	
User entered 'Oral (Oral)'	Gordon Bovee (b) (4)	22 Apr 2021 18:02:59
	(b) (4)	

**US3732249**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:22:42
	(b) (4)	
User entered empty.	Gordon Bovee (b) (4)	22 Apr 2021 18:02:59
	(b) (4)	

**US3732249**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:22:42
	(b) (4)	
User entered '59'	Gordon Bovee (b) (4)	22 Apr 2021 18:02:59
	(b) (4)	

**US3732249**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	22 Apr 2021 18:02:59

**US3732249**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:22:42
	(b) (4)	
User entered '15'	Gordon Bovee (b) (4)	22 Apr 2021 18:02:59
	(b) (4)	



**US3732249**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	22 Apr 2021 18:02:59

**US3732249**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:22:42
	(b) (4)	
User entered '130'	Gordon Bovee (b) (4)	22 Apr 2021 18:02:59
	(b) (4)	

**US3732249**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	22 Apr 2021 18:02:59

**US3732249**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:22:42
	(b) (4)	
User entered '68'	Gordon Bovee (b) (4)	22 Apr 2021 18:02:59
	(b) (4)	

**US3732249**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:34:18**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	22 Apr 2021 18:02:59

**US3732249**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:34:18**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:22:42
	(b) (4)	
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	22 Apr 2021 18:02:27
	(b) (4)	

**US3732249**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:34:18**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:22:42
	(b) (4)	
User entered '22 Apr 2021'	Gordon Bovee (b) (4)	22 Apr 2021 18:02:27
	(b) (4)	

**US3732249**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:34:18**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:22:42
	(b) (4)	
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	22 Apr 2021 18:03:14
	(b) (4)	



**US3732249**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:34:18**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:22:42
	(b) (4)	
User entered '22 Apr 2021'	Gordon Bovee (b) (4)	22 Apr 2021 18:03:14
	(b) (4)	

**US3732249**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:34:18**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:22:42
	(b) (4)	
User entered '10:13'	Gordon Bovee (b) (4)	22 Apr 2021 18:03:14
	(b) (4)	

**US3732249**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:34:18**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '22 Apr 2021 10:13'	System	22 Apr 2021 18:03:14

**US3732249**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 10 Jun 2021 09:34:18**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:32:01
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:18
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:15:58

**US3732249**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:34:18**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:36:58

US3732249

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:34:18

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:36:58
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 22:57:26
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal motility and defaecation conditions, HLT: Diarrhoea (excl infective), PT: Diarrhoea, LLT: Loose stools - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Dec 2020 19:08:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Dec 2020 19:08:31
Data point term sent to Coder	System	29 Dec 2020 19:07:52
Coding entries removed.	Amara Yilmaz (b) (4) (b) (4)	29 Dec 2020 19:07:41
User entered 'loose stools' reason for change: Data Entry Error	Amara Yilmaz (b) (4) (b) (4)	29 Dec 2020 19:07:41
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal motility and defaecation conditions, HLT: Diarrhoea (excl infective), PT: Diarrhoea, LLT: Diarrhea - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Oct 2020 21:17:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Oct 2020 21:17:39
Data point term sent to Coder	System	26 Oct 2020 21:16:54
User entered 'DIARRHEA'	(b) (4), (b) (6)	26 Oct 2020 21:16:53

**US3732249**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:36:58
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 22:57:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Oct 2020 21:16:53

**US3732249**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:36:58
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 22:57:36
User entered 'No (N)'	(b) (4), (b) (6)	26 Oct 2020 21:16:53



**US3732249**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:36:58
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 22:57:38
User entered 'No (N)'	(b) (4), (b) (6)	26 Oct 2020 21:16:53

**US3732249**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:36:58
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 22:57:41
User entered '22 Oct 2020'	(b) (4), (b) (6)	26 Oct 2020 21:16:53

**US3732249**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:36:58
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 22:57:42
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 21:16:53

**US3732249**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:34:18**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:36:58
User entered empty.	System	26 Oct 2020 21:16:53

US3732249

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:34:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:36:58
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 22:57:44
User closed query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if the AE has resolved and a stop date should be recorded. If yes, update accordingly. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 12:32:23
Query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if the AE has resolved and a stop date should be recorded. If yes, update accordingly. Otherwise, comment to confirm that this AE is still ongoing.' answered with 'data has been updated' (Site from DM).	Amara Yilmaz (b) (4) (b) (4)	29 Dec 2020 19:08:07
User entered 'No (N)' reason for change: Data Entry Error	Amara Yilmaz (b) (4) (b) (4)	29 Dec 2020 19:07:41
User opened query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if the AE has resolved and a stop date should be recorded. If yes, update accordingly. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	27 Dec 2020 04:04:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Oct 2020 21:16:53

US3732249

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:34:18

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:36:58
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 22:57:56
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	29 Dec 2020 19:07:54
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	29 Dec 2020 19:07:54
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	29 Dec 2020 19:07:41
User entered '27 Oct 2020' reason for change: Data Entry Error	Amara Yilmaz (b) (4)	29 Dec 2020 19:07:41
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 21:16:53

**US3732249**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:34:18**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:36:58
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 22:57:58
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 21:16:53

**US3732249**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:34:18**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:36:58
User entered empty.	System	26 Oct 2020 21:16:53



**US3732249**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:36:58
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 22:58:00
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	26 Oct 2020 21:16:53

**US3732249**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:36:58
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 22:58:06
User entered 'No (N)'	(b) (4), (b) (6)	26 Oct 2020 21:16:53

**US3732249**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:36:58
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 22:58:11
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 21:16:53

**US3732249**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:36:58
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 22:58:13
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 21:16:53

**US3732249**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:36:58
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 22:58:14
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 21:16:53

**US3732249**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:36:58
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Apr 2021 22:58:18
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 21:16:53

**US3732249**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:36:58
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 22:58:20
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 21:16:53

**US3732249**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:36:58
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 22:58:27
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 21:16:53



**US3732249**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:36:58
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 22:58:29
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 21:16:53

**US3732249**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:36:58
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 22:58:30
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 21:16:53

**US3732249**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:36:58
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 22:58:32
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 21:16:53

**US3732249**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:36:58
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 22:58:34
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 21:16:53

**US3732249**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:36:58
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 22:58:35
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	26 Oct 2020 21:16:53

**US3732249**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:36:58
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 22:58:37
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	26 Oct 2020 21:16:53

**US3732249**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:36:58
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 22:58:39
User entered 'None (NONE)'	(b) (4), (b) (6)	26 Oct 2020 21:16:53

**US3732249**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:34:18**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:36:58
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 22:58:45
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 21:16:53



**US3732249**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:36:58
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 22:58:47
User entered 'l'	(b) (4), (b) (6)	26 Oct 2020 21:16:53

**US3732249**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:36:58
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 22:58:48
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 21:16:53

US3732249

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:34:18

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:36:58
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	07 Apr 2021 22:58:50
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Amara Yilmaz (b) (4)	29 Dec 2020 19:07:54
Data Entry Error	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Oct 2020 21:17:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Oct 2020 21:17:07
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 21:17:07
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Oct 2020 21:16:53
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 21:16:53

**US3732249**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:34:18**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:36:58
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 22:58:52
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 21:16:53

**US3732249**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:36:58
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 22:58:53
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 21:16:53

**US3732249**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:36:58
User entered '0'	System	26 Oct 2020 21:16:53

**US3732249**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:36:58
User entered 'I'	System	26 Oct 2020 21:16:53

**US3732249**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:36:58



**US3732249**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:34:18**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 22:59:05
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 18:38:01
User entered	System	01 Feb 2021 18:37:54
'USA-US102-2021-mRNA-1273-P301000007'		
User entered 'New'	(b) (4), (b) (6)	01 Feb 2021 18:37:54

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:34:18

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 22:59:07
User coded data point as SOC: Vascular disorders, HLGT: Embolism and thrombosis, HLT: Peripheral embolism and thrombosis, PT: Deep vein thrombosis, LLT: Deep vein thrombosis leg - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Jan 2021 20:39:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Jan 2021 20:39:47
Data point term sent to Coder	System	31 Jan 2021 18:36:16
User entered 'deep vein thrombosis - right leg'	He (Helen) Pu (b) (4) (b) (4)	31 Jan 2021 18:35:34

**US3732249**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 22:59:09
User entered 'Yes (Y)'	He (Helen) Pu (b) (4) (b) (4)	31 Jan 2021 18:35:34

**US3732249**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 22:59:11
User entered 'No (N)'	He (Helen) Pu (b) (4) (b) (4)	31 Jan 2021 18:35:34

**US3732249**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 22:59:15
User entered 'No (N)'	He (Helen) Pu (b) (4) (b) (4)	31 Jan 2021 18:35:34

**US3732249**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 22:59:17
User entered '15 Jan 2021'	He (Helen) Pu (b) (4) (b) (4)	31 Jan 2021 18:35:34

US3732249

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:34:18

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 22:59:30
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	31 Jan 2021 18:36:04
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	31 Jan 2021 18:36:04
User entered empty; reason for change Data Entry Error	He (Helen) Pu (b) (4) (b) (4)	31 Jan 2021 18:36:04
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	31 Jan 2021 18:35:34
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	31 Jan 2021 18:35:34
User entered 'UN:UN' (non-conformant).	He (Helen) Pu (b) (4) (b) (4)	31 Jan 2021 18:35:34

**US3732249**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:34:18**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Jan 2021 18:36:04
User entered '15 Jan 2021 UN:UN' (non-conformant).	System	31 Jan 2021 18:35:34



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:34:18

[Ongoing?](#)

Audit	User	Time (GMT)
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. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 20:38:29
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved. A data entry is required in the EDC, please see the options available for this field.' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 16:59:44
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 16:59:37
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved. A data entry is required in the EDC, please see the options available for this field.' answered with 'requery after data lock' (Site from Safety).	Gordon Bovee (b) (4) (b) (4)	30 Apr 2021 22:38:35
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.' answered with 'AE is recovering. requery after data lock' (Site from Safety).	Gordon Bovee (b) (4) (b) (4)	30 Apr 2021 22:38:05
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved. A data entry is required in the EDC, please see the options available for this field.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 20:55:11
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 20:55:03
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:59:31
User entered 'Yes (Y)'	He (Helen) Pu (b) (4) (b) (4)	31 Jan 2021 18:35:34

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:34:18

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed 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. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 17:10:27
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. Please leave query open until information is available. ' answered with 'Re-query after data lock.' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 23:18:47
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. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 19:48:07
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 15:44:33
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.' answered with 'Per investigator AE is still on going ' (Site from Safety).	Gordon Bovee (b) (4) (b) (4)	22 Apr 2021 17:54:48
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 12:58:48
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:23:06
User closed query 'Per Source; Medical Records received and Subject Discharged from Hospital on 31-JAN-2021. Is this SAE Resolved?' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 23:22:56
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 18:56:00
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	09 Apr 2021 21:24:27

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:34:18

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per Source; Medical Records received and Subject Discharged from Hospital on 31-JAN-2021. Is this SAE Resolved?' answered with 'Open AE' (Site from CRA).	He (Helen) Pu (b) (4) (b) (4)	09 Apr 2021 20:16:29
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.' answered with 'Open AE' (Site from Safety).	He (Helen) Pu (b) (4) (b) (4)	09 Apr 2021 20:16:26
User opened query 'Per Source; Medical Records received and Subject Discharged from Hospital on 31-JAN-2021. Is this SAE Resolved?' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 23:00:32
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	24 Mar 2021 19:45:45
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	24 Mar 2021 19:45:45
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.' answered with 'Pending medical records. AE is currently still open until records are received.' (Site from Safety).	(b) (4), (b) (6)	23 Mar 2021 18:23:35
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 16:30:52
User entered empty.	He (Helen) Pu (b) (4) (b) (4)	31 Jan 2021 18:35:34

**US3732249**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:34:18**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:23:11
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 23:23:08
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:22:59
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
User entered empty.	He (Helen) Pu (b) (4)	31 Jan 2021 18:35:34

**US3732249**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:34:18**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Jan 2021 18:35:34

**US3732249**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:01:07
User entered 'Grade 3/Severe (Grade 3/Severe)'	He (Helen) Pu (b) (4) (b) (4)	31 Jan 2021 18:35:34

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:34:18

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:01:28
User entered 'Yes (Y)'	He (Helen) Pu (b) (4) (b) (4)	31 Jan 2021 18:35:34

**US3732249**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:01:31
User entered '0'	He (Helen) Pu (b) (4) (b) (4)	31 Jan 2021 18:35:34



**US3732249**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:01:33
User entered '0'	He (Helen) Pu (b) (4) (b) (4)	31 Jan 2021 18:35:34

US3732249

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:34:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:01:57
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	05 Apr 2021 07:08:36
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'admitted to hospital on 01/29/21 discharged 01/31/21 Patient was no admitted to ICU' (Site from System).	Linda Vega (b) (4) (b) (4)	01 Apr 2021 22:28:43
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	31 Jan 2021 18:35:34
User entered 'I'	He (Helen) Pu (b) (4) (b) (4)	31 Jan 2021 18:35:34

**US3732249**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:34:18**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:02:08
User entered '29 Jan 2021'	He (Helen) Pu (b) (4) (b) (4)	31 Jan 2021 18:35:34

US3732249

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:34:18

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 23:02:10
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 14:50:17
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'Updated' (Site from Safety).	Linda Vega (b) (4)	01 Apr 2021 22:22:01
	(b) (4)	
User entered '31 Jan 2021' reason for change: New Information	Linda Vega (b) (4)	01 Apr 2021 22:21:34
	(b) (4)	
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 16:30:33
User entered empty.	He (Helen) Pu (b) (4)	31 Jan 2021 18:35:34
	(b) (4)	

US3732249

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:34:18

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:02:13
User closed query 'Admitted to ICU?' is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	31 Jan 2021 18:36:04
Query 'Admitted to ICU?' is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).		31 Jan 2021 18:36:04
User entered empty; reason for change Data Entry Error	He (Helen) Pu (b) (4) (b) (4)	31 Jan 2021 18:36:04
User opened query 'Admitted to ICU?' is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	31 Jan 2021 18:35:34
User entered 'Unknown (UNK)'	He (Helen) Pu (b) (4) (b) (4)	31 Jan 2021 18:35:34

**US3732249**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:02:15
User entered empty.	He (Helen) Pu (b) (4) (b) (4)	31 Jan 2021 18:35:34

US3732249

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:34:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:02:17
User entered '0'	He (Helen) Pu (b) (4) (b) (4)	31 Jan 2021 18:35:34

**US3732249**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:02:19
User entered '0'	He (Helen) Pu (b) (4) (b) (4)	31 Jan 2021 18:35:34



**US3732249**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:02:21
User entered '0'	He (Helen) Pu (b) (4) (b) (4)	31 Jan 2021 18:35:34

**US3732249**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:02:22
User entered 'Not Related (NOT RELATED)'	He (Helen) Pu (b) (4) (b) (4)	31 Jan 2021 18:35:34

**US3732249**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:02:26
User entered 'Not Related (NOT RELATED)'	He (Helen) Pu (b) (4) (b) (4)	31 Jan 2021 18:35:34

**US3732249**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:23:16
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Un-verified.	He (Helen) Pu (b) (4)	09 Apr 2021 20:23:07
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Per Query Resolution	He (Helen) Pu (b) (4)	09 Apr 2021 20:23:07
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 23:02:28
User entered 'None (NONE)'	He (Helen) Pu (b) (4)	31 Jan 2021 18:35:34

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:34:18

None

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:02:30
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	25 Mar 2021 22:32:26
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	31 Jan 2021 18:35:34
User entered '0'	He (Helen) Pu (b) (4) (b) (4)	31 Jan 2021 18:35:34

**US3732249**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:02:31
User entered '1' reason for change: New Information	Gordon Bovee (b) (4)	25 Mar 2021 22:32:26
User entered '0'	(b) (4) He (Helen) Pu (b) (4) (b) (4)	31 Jan 2021 18:35:34

**US3732249**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:02:37
User entered '0'	He (Helen) Pu (b) (4) (b) (4)	31 Jan 2021 18:35:34

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:34:18

[Outcome](#)

Audit	User	Time (GMT)
User opened 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)	03 May 2021 20:38:34
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:22:08
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)	26 Apr 2021 17:10:56
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered by data change (Site from Safety).	System	23 Apr 2021 23:18:22
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 23:18:22
Signature has been broken.	(b) (4), (b) (6)	23 Apr 2021 23:18:22
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Apr 2021 23:18:22
User opened 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)	23 Apr 2021 19:49:01
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)	23 Apr 2021 15:44:52
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'Open AE - closing for data lock' (Site from Safety).	Gordon Bovee (b) (4)	22 Apr 2021 17:55:38
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 12:59:43
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:23:19



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:34:18

[Outcome](#)

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)	12 Apr 2021 18:55:28
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	12 Apr 2021 07:01:07
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'Open AE - closing for data lock' (Site from Safety).	He (Helen) Pu (b) (4)	09 Apr 2021 20:16:39
Query 'Data is required. Please complete.' answered with 'Open AE' (Site from System).	He (Helen) Pu (b) (4)	09 Apr 2021 20:16:32
User opened 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)	08 Feb 2021 16:31:23
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Jan 2021 18:35:34
User entered empty.	He (Helen) Pu (b) (4)	31 Jan 2021 18:35:34

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:34:18**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:02:42
User entered empty.	He (Helen) Pu (b) (4) (b) (4)	31 Jan 2021 18:35:34

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:34:18

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:23:23
User closed query 'PV Query: As the last dose of [study drug] was given on [09 Sep 2020], please update the action taken with [study drug] from none to not applicable. If study drug has been given since [date], please update the EDC accordingly.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 18:55:39
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 18:55:22
User closed query 'Per DM CLR: Narrative indicates that subject had "LOVENOX." However, this information is not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 07:01:12
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
Query 'PV Query: As the last dose of [study drug] was given on [09 Sep 2020], please update the action taken with [study drug] from none to not applicable. If study drug has been given since [date], please update the EDC accordingly.' answered with 'updated' (Site from Safety).	He (Helen) Pu (b) (4)	09 Apr 2021 20:37:26
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 'updated' (Site from Safety).	He (Helen) Pu (b) (4)	09 Apr 2021 20:37:21

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:34:18

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PATIENT CALLED SITE ON 30JAN2021, STATED HE IS IN HOSPITAL WITH A DEEP VEIN THROMBOSIS IN RIGHT LEG. STARTED 2 WEEKS AGO, EVENTUALLY DIAGNOSED AS DVT. ADMITTED 29JAN2021. ON LOVENOX. NO PROCEDURES. PATIENT STATES NO PHYSICAL EXAM.09Apr2021 MR narrative update: 30Jan2021 echo showed normal bilateral ventricles, no hemodynamically significant valve disease, and trivial posterior pericardial effusion. Bilateral duplex lower extremity ultrasound on 29Jan2021 showed a non-occlusive DVT in the right common femoral vein extending through the thigh into the popliteal vein and distal calf veins. Routine COVID-19 nasopharyngeal swab tested negative on 29Jan2021. Factor 5 Leiden mutation testing on 29Jan2021 was negative. D-Dimer was not tested per lab report.' reason for change: Per Query Resolution	He (Helen) Pu (b) (4) (b) (4)	09 Apr 2021 20:37:15
User opened query 'PV Query: As the last dose of [study drug] was given on [09 Sep 2020], please update the action taken with [study drug] from none to not applicable. If study drug has been given since [date], please update the EDC accordingly.' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 18:08:52
Query 'IQVIA Medical Review: Clarify if these symptoms/signs were associated with the reported events of anemia and shortness of breath or if they were the cause of these reported events. Please clarify if these signs/symptoms can be subsumed under a diagnosis.' canceled (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 17:55:17
Query 'IQVIA Medical Review: Please confirm if the following signs/symptoms experienced by the subject meet SAE reporting criteria. If so, they should be reported separately: generalized weakness, falls, dark tarry stools.' canceled (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 17:54:41
User opened query 'IQVIA Medical Review: Clarify if these symptoms/signs were associated with the reported events of anemia and shortness of breath or if they were the cause of these reported events. Please clarify if these signs/symptoms can be subsumed under a diagnosis.' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 17:02:25

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'IQVIA Medical Review: Please confirm if the following signs/symptoms experienced by the subject meet SAE reporting criteria. If so, they should be reported separately: generalized weakness, falls, dark tarry stools.' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 17:01:17
User closed query 'PV Query : Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 14:58:22
User closed query 'PV Query: Please clarify whether the subject has risk factors other than history of pulmonary embolism for development of DVT, (i.e. recent surgery, prolonged immobilization, non-therapeutic anticoagulation with Warfarin).' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 13:19:54
Query 'PV Query: Please clarify whether the subject has risk factors other than history of pulmonary embolism for development of DVT, (i.e. recent surgery, prolonged immobilization, non-therapeutic anticoagulation with Warfarin).' answered with 'Per hospital records, subject has history of DVT and PE. Subject was immobile for 2 weeks prior to hospitalization due to leg injury that occurred while walking. Per subject report at hospital, INR is usually between 1.5 and 2. ' (Site from Safety).	(b) (4), (b) (6)	07 Apr 2021 00:07:58
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 'COVID-19 testing (SARS-CoV-2 Real Time RT-PCR) on 29Jan2021 was negative.' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 23:42:31
Query 'Per DM CLR: Narrative indicates that subject had "LOVENOX." However, this information is not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' answered with 'Con Meds updated.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 22:58:44

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:34:18

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Narrative indicates that subject had "LOVENOX." However, this information is not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF.  ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 04:46:19
User opened query 'PV Query: Please clarify whether the subject has risk factors other than history of pulmonary embolism for development of DVT, (i.e. recent surgery, prolonged immobilization, non-therapeutic anticoagulation with Warfarin).' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 16:32:14
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 16:31:05
User opened query 'PV Query : Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 16:30:18
User entered 'patient called site on 30Jan2021, stated he is in hospital with a deep vein thrombosis in right leg. started 2 weeks ago, eventually diagnosed as DVT. Admitted 29Jan2021. On Lovenox. No procedures. Patient states no physical exam.'	He (Helen) Pu (b) (4) (b) (4)	31 Jan 2021 18:35:34

**US3732249**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Jan 2021 18:35:34

**US3732249**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Jan 2021 18:35:34



**US3732249**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	31 Jan 2021 18:35:34

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 10 Jun 2021 09:34:18**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:32:01
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 23:03:15
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'Yes (Y)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	02 Sep 2020 16:50:00

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:34:18

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:23
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:04:48
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: VITAMIN K ANTAGONISTS, PRODUCT: WARFARIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 16:16:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 16:16:42
Data point term sent to Coder	System	02 Sep 2020 16:51:31
User entered 'warfarin'	Lauren Arnett (b) (4) (b) (4)	02 Sep 2020 16:50:37

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:23
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered 'No (N)'	Lauren Arnett (b) (4)	02 Sep 2020 16:50:37
	(b) (4)	

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:23
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered 'pulmonary embolism'	Lauren Arnett (b) (4)	02 Sep 2020 16:50:37
	(b) (4)	

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:23
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered '4'	Lauren Arnett (b) (4)	02 Sep 2020 16:50:37
	(b) (4)	

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:23
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'mg (mg)'	Lauren Arnett (b) (4)	02 Sep 2020 16:50:37
	(b) (4)	

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:34:18**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:23
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered empty.	Lauren Arnett (b) (4)	02 Sep 2020 16:50:37
	(b) (4)	



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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:23
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered 'once daily (QD)'	Lauren Arnett (b) (4)	02 Sep 2020 16:50:37
	(b) (4)	

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:34:18**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:23
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered empty.	Lauren Arnett (b) (4) (b) (4)	02 Sep 2020 16:50:37

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:23
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered 'Oral (ORAL)'	Lauren Arnett (b) (4)	02 Sep 2020 16:50:37
	(b) (4)	

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:34:18**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:23
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered empty.	Lauren Arnett (b) (4)	02 Sep 2020 16:50:37
	(b) (4)	

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:23
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered 'un UNK 2008'	Lauren Arnett (b) (4)	02 Sep 2020 16:50:37

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:23
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered '0'	Lauren Arnett (b) (4)	02 Sep 2020 16:50:37
	(b) (4)	

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:23
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	06 Apr 2021 23:23:40
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	02 Sep 2020 16:50:37
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:34:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:23
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered '29 Jan 2021' reason for change: New Information	(b) (4), (b) (6)	06 Apr 2021 23:23:40
User entered empty.	Lauren Arnett (b) (4)	02 Sep 2020 16:50:37
	(b) (4)	



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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:23
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered 'No (N)'	Lauren Arnett (b) (4)	02 Sep 2020 16:50:37
	(b) (4)	

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:23
User entered '1'	System	02 Sep 2020 16:50:37

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:23
User entered '1'	System	02 Sep 2020 16:50:37

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:23
User entered '804 (804)'	System	02 Sep 2020 16:50:37

US3732249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:34:18

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:04:48
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Dec 2020 22:33:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Dec 2020 22:33:49
Data point term sent to Coder	System	07 Dec 2020 22:33:27
Coding entries removed.	Amara Yilmaz (b) (4) (b) (4)	07 Dec 2020 22:32:35
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 16:52:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 16:52:50
Data point term sent to Coder	System	02 Sep 2020 16:51:32
User entered 'calcium'	Lauren Arnett (b) (4) (b) (4)	02 Sep 2020 16:51:01

US3732249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:34:18

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered 'Yes (Y)' reason for change: New Information	Amara Yilmaz (b) (4) (b) (4)	07 Dec 2020 22:32:35
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	02 Sep 2020 16:51:01

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered 'vitamin deficiency' reason for change: New Information	Amara Yilmaz (b) (4) (b) (4)	07 Dec 2020 22:32:35
User entered 'nutritional supplement'	Lauren Arnett (b) (4) (b) (4)	02 Sep 2020 16:51:01

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered '1600'	Lauren Arnett (b) (4) (b) (4)	02 Sep 2020 16:51:01



**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered 'mg (mg)'	Lauren Arnett (b) (4) (b) (4)	02 Sep 2020 16:51:01

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:34:18**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered empty.	Lauren Arnett (b) (4) (b) (4)	02 Sep 2020 16:51:01

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered 'once daily (QD)'	Lauren Arnett (b) (4) (b) (4)	02 Sep 2020 16:51:01

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:34:18**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered empty.	Lauren Arnett (b) (4) (b) (4)	02 Sep 2020 16:51:01

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered 'Oral (ORAL)'	Lauren Arnett (b) (4) (b) (4)	02 Sep 2020 16:51:01

US3732249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:34:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered empty.	Lauren Arnett (b) (4) (b) (4)	02 Sep 2020 16:51:01

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered 'un UNK 2010'	Lauren Arnett (b) (4) (b) (4)	02 Sep 2020 16:51:01

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered '0'	Lauren Arnett (b) (4) (b) (4)	02 Sep 2020 16:51:01



**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	02 Sep 2020 16:51:01

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:34:18**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered empty.	Lauren Arnett (b) (4) (b) (4)	02 Sep 2020 16:51:01

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	02 Sep 2020 16:51:01

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 16:51:01

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 16:51:01

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 16:51:01

US3732249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:34:18

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:04:48
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Dec 2020 22:33:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Dec 2020 22:33:49
Data point term sent to Coder Coding entries removed.	System Amara Yilmaz (b) (4) (b) (4)	07 Dec 2020 22:33:27 07 Dec 2020 22:32:55
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 16:55:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 16:55:44
Data point term sent to Coder User entered 'vitamin D'	System Lauren Arnett (b) (4) (b) (4)	02 Sep 2020 16:54:42 02 Sep 2020 16:54:20

US3732249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:34:18

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered 'Yes (Y)' reason for change: New Information	Amara Yilmaz (b) (4) (b) (4)	07 Dec 2020 22:32:55
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	02 Sep 2020 16:54:20



US3732249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:34:18

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered 'VITAMIN deficiency' reason for change: New Information	Amara Yilmaz (b) (4) (b) (4)	07 Dec 2020 22:32:55
User entered 'vitamin supplement'	Lauren Arnett (b) (4) (b) (4)	02 Sep 2020 16:54:20

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:34:18**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered '1000' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Feb 2021 19:30:57
User entered '100'	Lauren Arnett (b) (4) (b) (4)	02 Sep 2020 16:54:20

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:34:18**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered 'IU (IU)'	Lauren Arnett (b) (4) (b) (4)	02 Sep 2020 16:54:20

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:34:18**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered empty.	Lauren Arnett (b) (4) (b) (4)	02 Sep 2020 16:54:20

US3732249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:34:18

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered 'once daily (QD)'	Lauren Arnett (b) (4) (b) (4)	02 Sep 2020 16:54:20

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:34:18**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered empty.	Lauren Arnett (b) (4) (b) (4)	02 Sep 2020 16:54:20

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:34:18**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered 'Oral (ORAL)'	Lauren Arnett (b) (4) (b) (4)	02 Sep 2020 16:54:20

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:34:18**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered empty.	Lauren Arnett (b) (4) (b) (4)	02 Sep 2020 16:54:20



**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:34:18**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered 'un UNK 2010'	Lauren Arnett (b) (4) (b) (4)	02 Sep 2020 16:54:20

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:34:18**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered '0'	Lauren Arnett (b) (4) (b) (4)	02 Sep 2020 16:54:20

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:34:18**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	02 Sep 2020 16:54:20

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:34:18**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered empty.	Lauren Arnett (b) (4) (b) (4)	02 Sep 2020 16:54:20

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:34:18**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	02 Sep 2020 16:54:20

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:34:18**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 16:54:20

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:34:18**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 16:54:20

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:34:18**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 16:54:20



US3732249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:34:18

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:27
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:04:48
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: OTHER DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, PRODUCT: SIMETICONE, PRODUCTSYNONYM: GAS-X - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Mar 2021 19:47:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Mar 2021 19:47:55
Data point term sent to Coder	System	10 Mar 2021 19:47:34
Coding entries removed.	He (Helen) Pu (b) (4) (b) (4)	10 Mar 2021 19:47:28
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: OTHER DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, PRODUCT: SIMETICONE, PRODUCTSYNONYM: GAS-X - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 21:19:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 21:19:30
Data point term sent to Coder	System	26 Oct 2020 21:18:56
User entered 'GAS-X'	(b) (4), (b) (6)	26 Oct 2020 21:18:16

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:34:18**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:27
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered 'No (N)'	(b) (4), (b) (6)	26 Oct 2020 21:18:16

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:34:18**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:27
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered 'loose stools' reason for change: Data Entry Error	He (Helen) Pu (b) (4)	10 Mar 2021 19:47:28
User entered 'DIARRHEA'	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	26 Oct 2020 21:18:16

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:34:18**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:27
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered '125'	(b) (4), (b) (6)	26 Oct 2020 21:18:16

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:34:18**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:27
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered 'mg (mg)'	(b) (4), (b) (6)	26 Oct 2020 21:18:16

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:34:18**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:27
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	07 Apr 2021 23:04:48
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 21:18:16

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:34:18**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:27
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered 'as needed (PRN)'	(b) (4), (b) (6)	26 Oct 2020 21:18:16

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:34:18**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:27
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 21:18:16



**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:34:18**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:27
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	26 Oct 2020 21:18:16

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:34:18**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:27
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 21:18:16

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:34:18**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:27
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered '22 Oct 2020'	(b) (4), (b) (6)	26 Oct 2020 21:18:16

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:34:18**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:27
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 21:18:16

US3732249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:34:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:27
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:04:48
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 20:40:47
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	He (Helen) Pu (b) (4) (b) (4)	10 Mar 2021 19:47:33
User entered 'No (N)' reason for change: New Information	He (Helen) Pu (b) (4) (b) (4)	10 Mar 2021 19:47:28
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 04:47:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Oct 2020 21:18:16

US3732249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:34:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:27
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
		07 Apr 2021 23:04:48
User entered '26 Oct 2020' reason for change: New Information	He (Helen) Pu (b) (4)	10 Mar 2021 19:47:28
User entered empty.	(b) (4)	(b) (4), (b) (6)
		26 Oct 2020 21:18:16

US3732249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:34:18

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:27
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:04:48
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 11:40:54
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' answered with 'Entry error; updated.' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 19:30:06
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Feb 2021 19:29:51
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 10:00:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Oct 2020 21:18:16

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:34:18**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:27
User entered empty.	System	26 Oct 2020 21:18:16



**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:34:18**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:27
User entered empty.	System	26 Oct 2020 21:18:16

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:34:18**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:27
User entered empty.	System	26 Oct 2020 21:18:16

US3732249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:34:18

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:04:48
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 20:30:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 20:30:30
Data point term sent to Coder	System	25 Mar 2021 20:29:57
User entered 'Eliquis'	Gordon Bovee (b) (4) (b) (4)	25 Mar 2021 20:29:12

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:34:18**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered 'No (N)'	Gordon Bovee (b) (4) (b) (4)	25 Mar 2021 20:29:12

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:34:18**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered 'DVT right leg'	Gordon Bovee (b) (4) (b) (4)	25 Mar 2021 20:29:12

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:34:18**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered '5'	Gordon Bovee (b) (4) (b) (4)	25 Mar 2021 20:29:12

US3732249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:34:18

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered 'mg (mg)'	Gordon Bovee (b) (4) (b) (4)	25 Mar 2021 20:29:12

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:34:18**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered empty.	Gordon Bovee (b) (4) (b) (4)	25 Mar 2021 20:29:12



**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:34:18**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered 'twice daily (BID)'	Gordon Bovee (b) (4) (b) (4)	25 Mar 2021 20:29:12

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:34:18**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered empty.	Gordon Bovee (b) (4) (b) (4)	25 Mar 2021 20:29:12

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:34:18**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered 'Oral (ORAL)'	Gordon Bovee (b) (4) (b) (4)	25 Mar 2021 20:29:12

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:34:18**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered empty.	Gordon Bovee (b) (4) (b) (4)	25 Mar 2021 20:29:12

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:34:18**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered '31 Jan 2021'	Gordon Bovee (b) (4) (b) (4)	25 Mar 2021 20:29:12

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:34:18**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered '0'	Gordon Bovee (b) (4) (b) (4)	25 Mar 2021 20:29:12

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:34:18**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered 'Yes (Y)'	Gordon Bovee (b) (4) (b) (4)	25 Mar 2021 20:29:12

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:34:18**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered empty.	Gordon Bovee (b) (4) (b) (4)	25 Mar 2021 20:29:12



**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:34:18**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered 'No (N)'	Gordon Bovee (b) (4) (b) (4)	25 Mar 2021 20:29:12

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:34:18**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	25 Mar 2021 20:29:12

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:34:18**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Mar 2021 20:29:12

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:34:18**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Mar 2021 20:29:12

US3732249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:34:18

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:30
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:04:48
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN SODIUM, PRODUCTSYNONYM: LOVENOX [ENOXAPARIN SODIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Mar 2021 08:02:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Mar 2021 08:02:21
Data point term sent to Coder	System	30 Mar 2021 18:51:56
User entered 'Lovenox'	He (Helen) Pu (b) (4) (b) (4)	30 Mar 2021 18:51:27

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:34:18**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:30
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered 'No (N)'	He (Helen) Pu (b) (4)	30 Mar 2021 18:51:27
	(b) (4)	

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:34:18**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:30
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered 'DVT right leg'	He (Helen) Pu (b) (4)	30 Mar 2021 18:51:27
	(b) (4)	

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:34:18**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:30
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered '80'	He (Helen) Pu (b) (4) (b) (4)	30 Mar 2021 18:51:27



**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:34:18**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:30
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered 'mg (mg)'	He (Helen) Pu (b) (4)	30 Mar 2021 18:51:27
	(b) (4)	

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:34:18**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:30
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered empty.	He (Helen) Pu (b) (4)	30 Mar 2021 18:51:27
	(b) (4)	

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:34:18**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:30
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered 'twice daily (BID)'	He (Helen) Pu (b) (4)	30 Mar 2021 18:51:27
	(b) (4)	

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:34:18**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:30
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered empty.	He (Helen) Pu (b) (4)	30 Mar 2021 18:51:27
	(b) (4)	

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:34:18**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:30
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered 'Subcutaneous (SUBCUTANEOUS)'	He (Helen) Pu (b) (4)	30 Mar 2021 18:51:27
	(b) (4)	

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:34:18**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:30
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
		07 Apr 2021 23:04:48
User entered empty.	He (Helen) Pu (b) (4)	30 Mar 2021 18:51:27
	(b) (4)	

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:34:18**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:30
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered '29 Jan 2021'	He (Helen) Pu (b) (4)	30 Mar 2021 18:51:27
	(b) (4)	

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:34:18**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:30
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered '0'	He (Helen) Pu (b) (4)	30 Mar 2021 18:51:27
	(b) (4)	



**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:34:18**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:30
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered 'No (N)'	He (Helen) Pu (b) (4)	30 Mar 2021 18:51:27
	(b) (4)	

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:34:18**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:30
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '31 Jan 2021'	He (Helen) Pu (b) (4)	30 Mar 2021 18:51:27
	(b) (4)	

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:34:18**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:30
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered 'No (N)'	He (Helen) Pu (b) (4)	30 Mar 2021 18:51:27
	(b) (4)	

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:34:18**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:30
User entered '2'	System	30 Mar 2021 18:51:27

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:34:18**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:30
User entered '1'	System	30 Mar 2021 18:51:27

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:34:18**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:30
User entered '804 (804)'	System	30 Mar 2021 18:51:27

US3732249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:34:18

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:32
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 18:05:52
User closed query 'Please refer to Medical Records for additional ConMeds that need to be added to ConMed Log during Subjects Hospitalization dated 29-31 JAN 2021.' (Site from CRA).	(b) (4), (b) (6)	27 Apr 2021 18:05:46
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
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: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Apr 2021 20:29:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Apr 2021 20:29:08
Data point term sent to Coder	System	09 Apr 2021 20:28:17
User entered 'FAMOTIDINE' reason for change: Data Entry Error	He (Helen) Pu (b) (4)	09 Apr 2021 20:28:15
Query 'Please refer to Medical Records for additional ConMeds that need to be added to ConMed Log during Subjects Hospitalization dated 29-31 JAN 2021.' answered by data change (Site from CRA).	System	09 Apr 2021 20:28:09
DataPoint Un-verified.	He (Helen) Pu (b) (4)	09 Apr 2021 20:28:09
Coding entries removed.	He (Helen) Pu (b) (4)	09 Apr 2021 20:28:09
User entered 'FAMOTIDINE - other cms during hospitalization not administered (see pages 11-12)' reason for change: Data Entry Error	He (Helen) Pu (b) (4)	09 Apr 2021 20:28:09
User opened query 'Please refer to Medical Records for additional ConMeds that need to be added to ConMed Log during Subjects Hospitalization dated 29-31 JAN 2021.' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 23:12:06
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 23:04:48

US3732249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:34:18

[Name of Medication](#)

Audit	User	Time (GMT)
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: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Mar 2021 07:50:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Mar 2021 07:50:26
Data point term sent to Coder	System	30 Mar 2021 18:52:57
User entered 'famotidine'	He (Helen) Pu (b) (4) (b) (4)	30 Mar 2021 18:52:25



**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:34:18**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:32
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered 'Yes (Y)'	He (Helen) Pu (b) (4)	30 Mar 2021 18:52:25
	(b) (4)	

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:34:18**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:32
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered 'GI prophylaxis'	He (Helen) Pu (b) (4)	30 Mar 2021 18:52:25
	(b) (4)	

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:34:18**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:32
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered '20'	He (Helen) Pu (b) (4) (b) (4)	30 Mar 2021 18:52:25

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:34:18**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:32
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered 'mg (mg)'	He (Helen) Pu (b) (4)	30 Mar 2021 18:52:25
	(b) (4)	

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:34:18**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:32
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered empty.	He (Helen) Pu (b) (4)	30 Mar 2021 18:52:25
	(b) (4)	

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:34:18**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:32
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered 'twice daily (BID)'	He (Helen) Pu (b) (4)	30 Mar 2021 18:52:25
	(b) (4)	

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:34:18**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:32
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered empty.	He (Helen) Pu (b) (4)	30 Mar 2021 18:52:25
	(b) (4)	

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:34:18**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:32
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered 'Oral (ORAL)'	He (Helen) Pu (b) (4)	30 Mar 2021 18:52:25
	(b) (4)	



**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:34:18**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:32
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered empty.	He (Helen) Pu (b) (4)	30 Mar 2021 18:52:25
	(b) (4)	

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:34:18**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:32
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered '29 Jan 2021'	He (Helen) Pu (b) (4)	30 Mar 2021 18:52:25
	(b) (4)	

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:34:18**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:32
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered '0'	He (Helen) Pu (b) (4) (b) (4)	30 Mar 2021 18:52:25

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:34:18**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:32
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered 'No (N)'	He (Helen) Pu (b) (4)	30 Mar 2021 18:52:25
	(b) (4)	

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:34:18**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:32
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '31 Jan 2021'	He (Helen) Pu (b) (4)	30 Mar 2021 18:52:25
	(b) (4)	

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:34:18**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:32
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 23:04:48
User entered 'No (N)'	He (Helen) Pu (b) (4)	30 Mar 2021 18:52:25
	(b) (4)	

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:34:18**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:32
User entered '2'	System	30 Mar 2021 18:52:25

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:34:18**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:32
User entered '1'	System	30 Mar 2021 18:52:25



**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:34:18**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:23:32
User entered '804 (804)'	System	30 Mar 2021 18:52:25

US3732249

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:34:18

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:22:08
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: TETANUS VACCINES, PRODUCT: TETANUS VACCINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	22 Apr 2021 19:44:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 19:44:59
Data point term sent to Coder	System	22 Apr 2021 19:44:22
User entered 'tetanus vaccine'	Gordon Bovee (b) (4) (b) (4)	22 Apr 2021 19:43:52

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:34:18**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:22:08
	(b) (4)	
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	22 Apr 2021 19:43:52
	(b) (4)	

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:34:18**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:22:08
User entered 'tetanus'	(b) (4) Gordon Bovee (b) (4) (b) (4)	22 Apr 2021 19:43:52

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:34:18**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:22:08
User entered '0.5'	(b) (4) Gordon Bovee (b) (4)	22 Apr 2021 19:43:52

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:34:18**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:22:08
	(b) (4)	
User entered 'mL (mL)'	Gordon Bovee (b) (4)	22 Apr 2021 19:43:52
	(b) (4)	

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:34:18**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:22:08
User entered empty.	(b) (4) Gordon Bovee (b) (4) (b) (4)	22 Apr 2021 19:43:52

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:34:18**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:22:08
User entered 'once (ONCE)'	(b) (4) Gordon Bovee (b) (4)	22 Apr 2021 19:43:52
	(b) (4)	



**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:34:18**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:22:08
User entered empty.	(b) (4) Gordon Bovee (b) (4) (b) (4)	22 Apr 2021 19:43:52

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:34:18**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:22:08
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Gordon Bovee (b) (4) (b) (4)	22 Apr 2021 19:43:52

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:34:18**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:22:08
	(b) (4)	
User entered empty.	Gordon Bovee (b) (4)	22 Apr 2021 19:43:52
	(b) (4)	

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:34:18**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:22:08
	(b) (4)	
User entered '08 Apr 2021'	Gordon Bovee (b) (4)	22 Apr 2021 19:43:52
	(b) (4)	

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:34:18**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:22:08
	(b) (4)	
User entered '0'	Gordon Bovee (b) (4)	22 Apr 2021 19:43:52
	(b) (4)	

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:34:18**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:22:08
	(b) (4)	
User entered 'No (N)'	Gordon Bovee (b) (4)	22 Apr 2021 19:43:52
	(b) (4)	

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:34:18**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:22:08
	(b) (4)	
User entered '08 Apr 2021'	Gordon Bovee (b) (4)	22 Apr 2021 19:43:52
	(b) (4)	

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:34:18**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:22:08
	(b) (4)	
User entered 'No (N)'	Gordon Bovee (b) (4)	22 Apr 2021 19:43:52
	(b) (4)	



**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:34:18**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Apr 2021 19:43:52

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:34:18**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Apr 2021 19:43:52

**US3732249**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:34:18**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Apr 2021 19:43:52

US3732249

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:34:18

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:32:01
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Un-verified.	(b) (4)	
	He (Helen) Pu (b) (4)	09 Apr 2021 20:37:43
User entered 'Yes (Y)' reason for change: New Information	(b) (4)	
	He (Helen) Pu (b) (4)	09 Apr 2021 20:37:43
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:13:52
User entered 'No (N)'	Gordon Bovee (b) (4)	25 Mar 2021 20:27:13
	(b) (4)	

**US3732249**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 09:34:18**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
User entered '30 Jan 2021'	(b) (4) He (Helen) Pu (b) (4)	09 Apr 2021 20:38:00

**US3732249**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
User entered 'echocardiogram'	(b) (4) He (Helen) Pu (b) (4)	09 Apr 2021 20:38:00
	(b) (4)	

**US3732249**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) He (Helen) Pu (b) (4) (b) (4)	09 Apr 2021 20:38:00

US3732249

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:34:18

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
User entered empty.	(b) (4) He (Helen) Pu (b) (4) (b) (4)	09 Apr 2021 20:38:00



US3732249

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:34:18

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:54
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
User entered '29 Jan 2021'	(b) (4) He (Helen) Pu (b) (4) (b) (4)	09 Apr 2021 20:38:15

US3732249

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:34:18

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:54
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
User entered 'bilateral duplex lower extremity ultrasound'	(b) (4) He (Helen) Pu (b) (4) (b) (4)	09 Apr 2021 20:38:15

**US3732249**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:54
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) He (Helen) Pu (b) (4)	09 Apr 2021 20:38:15

US3732249

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:34:18

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:39:54
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
User entered empty.	(b) (4) He (Helen) Pu (b) (4)	09 Apr 2021 20:38:15

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'USA-US102-2021-MRNA-1273-P301000007'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'Yes (Y)'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'No (N)'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'No (N)'	System	01 Feb 2021 18:37:54



**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'Yes (Y)'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'No (N)'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'No (N)'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'No (N)'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'Scott'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'Overcash'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered '5565 Grossmont Center Dr'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'La Mesa'	System	01 Feb 2021 18:37:54



**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'CA'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered '91942'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 14:51:18
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'US'	(b) (4) System	01 Feb 2021 18:38:24

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	26 Apr 2021 17:11:58
User entered '4'	System	12 Apr 2021 18:56:38
User entered '3'	System	02 Apr 2021 14:51:30
User entered '2'	System	26 Mar 2021 15:25:54
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
	(b) (4)	
User entered '1'	System	01 Feb 2021 18:38:24

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'USA-US102-2021-MRNA-1273-P301000007'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'Yes (Y)'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'No (N)'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'No (N)'	System	01 Feb 2021 18:37:54



**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'Yes (Y)'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'No (N)'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'No (N)'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'No (N)'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'Scott'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'Overcash'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered '5565 Grossmont Center Dr'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'La Mesa'	System	01 Feb 2021 18:37:54



**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'CA'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered '91942'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 14:51:18
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'US'	(b) (4) System	01 Feb 2021 18:38:24

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	26 Apr 2021 17:11:58
User entered '4'	System	12 Apr 2021 18:56:38
User entered '3'	System	02 Apr 2021 14:51:30
User entered '2'	System	26 Mar 2021 15:25:54
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
	(b) (4)	
User entered '1'	System	01 Feb 2021 18:38:24

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 09:34:18**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered '01/Feb/2021 13:38'	(b) (4) System	01 Feb 2021 18:38:24

US3732249

Folder: SAE USA-US102-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:34:18

**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)	07 Apr 2021 22:54:06
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 14:51:18
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'I'	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:24

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'USA-US102-2021-MRNA-1273-P301000007'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'Yes (Y)'	System	01 Feb 2021 18:37:54



**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'No (N)'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'No (N)'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'Yes (Y)'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'No (N)'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'No (N)'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'No (N)'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'Scott'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'Overcash'	System	01 Feb 2021 18:37:54



**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered '5565 Grossmont Center Dr'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'La Mesa'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'CA'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered '91942'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 14:51:18
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'US'	(b) (4) System	01 Feb 2021 18:38:24

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	26 Apr 2021 17:11:58
User entered '4'	System	12 Apr 2021 18:56:38
User entered '3'	System	02 Apr 2021 14:51:30
User entered '2'	System	26 Mar 2021 15:25:54
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
	(b) (4)	
User entered '1'	System	01 Feb 2021 18:38:24

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 09:34:18**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 22:54:06
User entered '26/Mar/2021 11:25'	System	26 Mar 2021 15:25:54

US3732249

Folder: SAE USA-US102-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:34:18

**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.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 22:54:06
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 14:51:18
User entered 'I'	(b) (4), (b) (6)	26 Mar 2021 15:25:54



**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'USA-US102-2021-MRNA-1273-P301000007'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'Yes (Y)'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'No (N)'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'No (N)'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'Yes (Y)'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'No (N)'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'No (N)'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'No (N)'	System	01 Feb 2021 18:37:54



**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'Scott'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'Overcash'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered '5565 Grossmont Center Dr'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'La Mesa'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'CA'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered '91942'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 14:51:18
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'US'	(b) (4) System	01 Feb 2021 18:38:24

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	26 Apr 2021 17:11:58
User entered '4'	System	12 Apr 2021 18:56:38
User entered '3'	System	02 Apr 2021 14:51:30
User entered '2'	System	26 Mar 2021 15:25:54
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
	(b) (4)	
User entered '1'	System	01 Feb 2021 18:38:24



**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form (3)**

**Generated On: 10 Jun 2021 09:34:18**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 22:54:06
User entered '02/Apr/2021 10:51'	System	02 Apr 2021 14:51:30

US3732249

Folder: SAE USA-US102-2021-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:34:18

**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.	Scott Overcash (b) (4)	09 Apr 2021 21:24:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 22:54:06
User entered 'I'	(b) (4), (b) (6)	02 Apr 2021 14:51:30

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'USA-US102-2021-MRNA-1273-P301000007'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'Yes (Y)'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'No (N)'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'No (N)'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'Yes (Y)'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'No (N)'	System	01 Feb 2021 18:37:54



**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'No (N)'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'No (N)'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'Scott'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'Overcash'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered '5565 Grossmont Center Dr'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'La Mesa'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'CA'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered '91942'	System	01 Feb 2021 18:37:54



**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 14:51:18
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'US'	(b) (4) System	01 Feb 2021 18:38:24

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	26 Apr 2021 17:11:58
User entered '4'	System	12 Apr 2021 18:56:38
User entered '3'	System	02 Apr 2021 14:51:30
User entered '2'	System	26 Mar 2021 15:25:54
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
	(b) (4)	
User entered '1'	System	01 Feb 2021 18:38:24

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form (4)**

**Generated On: 10 Jun 2021 09:34:18**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:22:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 23:22:30
User entered '12/Apr/2021 14:56'	System	12 Apr 2021 18:56:38

US3732249

Folder: SAE USA-US102-2021-MRNA-1273-P301000007

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:34:18

**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.	Scott Overcash (b) (4)	28 Apr 2021 22:22:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 23:22:30
User entered 'I'	(b) (4), (b) (6)	12 Apr 2021 18:56:38

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'USA-US102-2021-MRNA-1273-P301000007'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'Yes (Y)'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'No (N)'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'No (N)'	System	01 Feb 2021 18:37:54



**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'Yes (Y)'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'No (N)'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'No (N)'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'No (N)'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'Scott'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'Overcash'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered '5565 Grossmont Center Dr'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'La Mesa'	System	01 Feb 2021 18:37:54



**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered 'CA'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Feb 2021 18:38:13
User entered '91942'	System	01 Feb 2021 18:37:54

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 22:54:06
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 14:51:18
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
User entered 'US'	(b) (4) System	01 Feb 2021 18:38:24

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:34:18**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	26 Apr 2021 17:11:58
User entered '4'	System	12 Apr 2021 18:56:38
User entered '3'	System	02 Apr 2021 14:51:30
User entered '2'	System	26 Mar 2021 15:25:54
User signature succeeded.	Scott Overcash (b) (4)	25 Feb 2021 02:01:08
	(b) (4)	
User entered '1'	System	01 Feb 2021 18:38:24

**US3732249**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000007**

**Form: Safety Report Form (5)**

**Generated On: 10 Jun 2021 09:34:18**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:22:42
User entered '26/Apr/2021 10:11'	(b) (4) System	26 Apr 2021 17:11:58

US3732249

Folder: SAE USA-US102-2021-MRNA-1273-P301000007

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:34:18

**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.	Scott Overcash (b) (4)	28 Apr 2021 22:22:42
User entered 'I'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 17:11:58