

US3732304 (Prod: eStudySite - La Mesa - PPDS)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:26:54

All time stamps listed in this document are displayed in GMT

US3732304

Form: Participant Creation

Data signed: (b) (4) 26 Feb 2021 01:40:36

Generated On: 10 Jun 2021 09:26:54

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[Participant ID](#)

US3732304

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

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US3732304

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 01:40:45

Generated On: 10 Jun 2021 09:26:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 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) 26 Feb 2021 01:40:38

Generated On: 10 Jun 2021 09:26:54

Date of Birth (MMM yyyy)	(b) (6) 1964
Age	55
Age Units	YEARS
Age (Derived)	56
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	True
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 26 Feb 2021 01:40:38

Generated On: 10 Jun 2021 09:26:54

Date of Informed Consent ( <i>dd MMM yyyy</i> )	09 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) 26 Feb 2021 01:40:38

Generated On: 10 Jun 2021 09:26:54

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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) 26 Feb 2021 01:40:45

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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) 26 Feb 2021 01:40:38

Generated On: 10 Jun 2021 09:26:54

Condition	ENVIRONMENTAL ALLERGIES
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: Medical History (2)

Data signed: (b) (4) 26 Feb 2021 01:40:38

Generated On: 10 Jun 2021 09:26:54

Condition	ALLERGY TO PET DANDER
Start date (dd MMM yyyy)	UN UNK 1978
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 1978
Start Year (derived)	1978
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 26 Feb 2021 01:40:38

Generated On: 10 Jun 2021 09:26:54

Condition	ASTHMA
Start date (dd MMM yyyy)	UN UNK 1974
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 1974
Start Year (derived)	1974
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 26 Feb 2021 01:40:38

Generated On: 10 Jun 2021 09:26:54

Condition	GASTROESOPHAGEAL REFLUX DISEASE
Start date (dd MMM yyyy)	UN UNK 1998
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 1998
Start Year (derived)	1998
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 26 Feb 2021 01:40:38

Generated On: 10 Jun 2021 09:26:54

Condition	MYOPIA BILATERAL
Start date (dd MMM yyyy)	UN UNK 1974
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 1974
Start Year (derived)	1974
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 26 Feb 2021 01:40:38

Generated On: 10 Jun 2021 09:26:54

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 26 Feb 2021 01:40:38

Generated On: 10 Jun 2021 09:26:54

Condition	CHRONIC BACK PAIN
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 (8)

Data signed: (b) (4) 26 Feb 2021 01:40:38

Generated On: 10 Jun 2021 09:26:54

Condition	INSOMNIA
Start date (dd MMM yyyy)	UN UNK 1996
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 1996
Start Year (derived)	1996
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 26 Feb 2021 01:40:38

Generated On: 10 Jun 2021 09:26:54

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 1996
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 1996
Start Year (derived)	1996
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 26 Feb 2021 01:40:38

Generated On: 10 Jun 2021 09:26:54

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

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 26 Feb 2021 01:40:38

Generated On: 10 Jun 2021 09:26:54

Condition	CYSTOCELE SURGERY
Start date (dd MMM yyyy)	16 NOV 2013
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)	16 NOV 2013
Stop date completely unknown	False
Start Month and Year (derived)	NOV 2013
Start Year (derived)	2013
Stop Month and Year (derived)	NOV 2013
Stop Year (derived)	2013

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 26 Feb 2021 01:40:38

Generated On: 10 Jun 2021 09:26:54

Condition	CYSTOCELE SURGERY
Start date (dd MMM yyyy)	17 AUG 2015
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)	17 AUG 2015
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2015
Start Year (derived)	2015
Stop Month and Year (derived)	AUG 2015
Stop Year (derived)	2015

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 26 Feb 2021 01:40:38

Generated On: 10 Jun 2021 09:26:54

Condition	RIGHT TRIGGER FINGER RELEASE
Start date (dd MMM yyyy)	12 JUN 2020
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)	12 JUN 2020
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	JUN 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 26 Feb 2021 01:40:38

Generated On: 10 Jun 2021 09:26:54

Condition	CHRONIC NECK PAIN
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 (15)

Data signed: (b) (4) 26 Feb 2021 01:40:38

Generated On: 10 Jun 2021 09:26:54

Condition	CYSTOCELE
Start date (dd MMM yyyy)	16 NOV 2013
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)	16 NOV 2013
Stop date completely unknown	False
Start Month and Year (derived)	NOV 2013
Start Year (derived)	2013
Stop Month and Year (derived)	NOV 2013
Stop Year (derived)	2013

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 26 Feb 2021 01:40:38

Generated On: 10 Jun 2021 09:26:54

Condition	CYSTOCELE
Start date (dd MMM yyyy)	17 AUG 2015
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)	17 AUG 2015
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2015
Start Year (derived)	2015
Stop Month and Year (derived)	AUG 2015
Stop Year (derived)	2015

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 26 Feb 2021 01:40:38

Generated On: 10 Jun 2021 09:26:54

Condition	RIGHT CARPAL TUNNEL RELEASE
Start date (dd MMM yyyy)	12 JUN 2020
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)	12 JUN 2020
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	JUN 2020
Stop Year (derived)	2020



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Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 26 Feb 2021 01:40:38

Generated On: 10 Jun 2021 09:26:54

Condition	RIGHT CARPAL TUNNEL
Start date (dd MMM yyyy)	UN UNK 1994
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	12 JUN 2020
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1994
Start Year (derived)	1994
Stop Month and Year (derived)	JUN 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 26 Feb 2021 01:40:45

Generated On: 10 Jun 2021 09:26:54

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	09 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	14:48 (24 HR)
Vital Signs Date and Time (derived)	09 SEP 2020 14:48
Height ( <i>xxx.x</i> )	167.0 cm
Weight ( <i>xxx.x</i> )	79.0 kg
BMI ( <i>xxx.x</i> )	28.32658 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) 26 Feb 2021 01:40:45

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

09 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: Childbearing Potential

Data signed: (b) (4) 26 Feb 2021 01:40:38

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Date of assessment (dd MMM yyyy) 09 SEP 2020

Is the participant of childbearing potential? Yes ☒  
No ☐

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

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

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

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) \_\_\_\_\_

Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 26 Feb 2021 01:40:45

Generated On: 10 Jun 2021 09:26:54

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (dd MMM yyyy)	09 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 26 Feb 2021 01:40:45

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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**

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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) 26 Feb 2021 01:40:45

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 01:40:45

Generated On: 10 Jun 2021 09:26:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 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) 26 Feb 2021 01:40:45

Generated On: 10 Jun 2021 09:26:54

What was the date of randomization? (dd MMM yyyy) 09 SEP 2020

What was the participant's randomization number? 112827

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) 26 Feb 2021 01:40:45

Generated On: 10 Jun 2021 09:26:54

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) 26 Feb 2021 01:40:45

Generated On: 10 Jun 2021 09:26:54

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)	09 SEP 2020
Time of assessment (00:00-23:59)	14:48 (24 HR)
Vital Signs Date and Time (derived)	09 SEP 2020 14:48
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Feb 2021 01:40:45

Generated On: 10 Jun 2021 09:26:54

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)	09 SEP 2020
Time of assessment (00:00-23:59)	16:37 (24 HR)
Vital Signs Date and Time (derived)	09 SEP 2020 16:37
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	89 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 26 Feb 2021 01:40:45

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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: Pregnancy Test

Data signed: (b) (4) 26 Feb 2021 01:40:45

Generated On: 10 Jun 2021 09:26:54

Was the pregnancy test performed? Yes ☐  
No ☒

Date of test (dd MMM yyyy) \_\_\_\_\_

Test performed Urine ☐  
Serum ☐

Result Positive ☐  
Negative ☐

Was FSH sample collected? Yes ☐  
No ☒

Collection date \_\_\_\_\_

Collection time \_\_\_\_\_

Collection date and time (derived) \_\_\_\_\_

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 26 Feb 2021 01:40:45

Generated On: 10 Jun 2021 09:26:54

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) 09 SEP 2020

What was the treatment time? (00:00-23:59) 16:07 (24 HR)

Treatment Date and Time (derived) 09 SEP 2020 16:07

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) 26 Feb 2021 01:40:45

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Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	09 SEP 2020
Collection time (00:00-23:59)	15:27 (24 HR)
Collection date and time (derived)	09 SEP 2020 15:27



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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Feb 2021 01:40:45

Generated On: 10 Jun 2021 09:26:54

Collection date (dd MMM yyyy)			09 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:23	09 SEP 2020 15:23
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 01:40:45

Generated On: 10 Jun 2021 09:26:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:26:54

**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

98.4 °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

09 SEP 2020 16:43

PC Open Date & Time

09 SEP 2020 16:27

PC Close Date & Time

09 SEP 2020 18:57

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:26:54

**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.

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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

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

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

To **TREAT** pain or fever that has already occurred

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

09 SEP 2020 19:52

PC Close Date & Time

10 SEP 2020 11:59

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:26:54

**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

99.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 19:04

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:26:54

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**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.9 °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

11 SEP 2020 22:00

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:26:54

**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

98.1 °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):

To **TREAT** pain or fever that has already occurred

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

12 SEP 2020 22:30

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:26:54

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**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

98.4 °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

13 SEP 2020 21:45

---

PC Open Date & Time

13 SEP 2020 12:00

---

PC Close Date & Time

14 SEP 2020 11:59

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US3732304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:26:54

**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.

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 18:03

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:26:54

**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.

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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.

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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

99.1 °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

15 SEP 2020 19:05

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:26:54

**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

09 SEP 2020 16:43

PC Open Date & Time

09 SEP 2020 16:27

PC Close Date & Time

09 SEP 2020 18:57

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:26:54

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

PC Open Date & Time

09 SEP 2020 19:52

PC Close Date & Time

10 SEP 2020 11:59

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:26:54

**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

10 SEP 2020 19:05

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:26:54

**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

11 SEP 2020 21:43

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:26:54

**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

12 SEP 2020 22:30

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:26:54

**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

13 SEP 2020 21:46

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59



US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:26:54

**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

14 SEP 2020 18:02

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:26:54

**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

15 SEP 2020 19:05

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:26:54

**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 ☐

US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:26:54

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

No ☒

Yes ☐

PC Time stamp	09 SEP 2020 16:44
PC Open Date & Time	09 SEP 2020 16:27
PC Close Date & Time	09 SEP 2020 18:57

US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:26:54

**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 ☐

US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:26:54

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

09 SEP 2020 19:52

PC Close Date & Time

10 SEP 2020 11:59

US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:26:54

**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 ☒

US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:26:54

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 19:05
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59



US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:26:54

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 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:26:54

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 21:44
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:26:54

**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 ☒

US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:26:54

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 22:31
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:26:54

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:26:54

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 21:46
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:26:54

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 ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:26:54

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



US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:26:54

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:26:54

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 19:06
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3732304

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 10 Jun 2021 09:26:54

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

None ☒

**FATIGUE**

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

17 SEP 2020 10:32

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3732304

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 09:26:54

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	17 SEP 2020 10:33
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3732304

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 01:40:37

Generated On: 10 Jun 2021 09:26:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3732304

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 01:40:37

Generated On: 10 Jun 2021 09:26:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732304

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 01:40:37

Generated On: 10 Jun 2021 09:26:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3732304

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 01:40:37

Generated On: 10 Jun 2021 09:26:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3732304

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 01:40:37

Generated On: 10 Jun 2021 09:26:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3732304

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 01:40:37

Generated On: 10 Jun 2021 09:26:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732304

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 01:40:45

Generated On: 10 Jun 2021 09:26:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	07 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	VISIT2

US3732304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Feb 2021 01:40:45

Generated On: 10 Jun 2021 09:26:54

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)	07 OCT 2020
Time of assessment (00:00-23:59)	13:25 (24 HR)
Vital Signs Date and Time (derived)	07 OCT 2020 13:25
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	97 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3732304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Feb 2021 01:40:45

Generated On: 10 Jun 2021 09:26:54

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)	07 OCT 2020
Time of assessment (00:00-23:59)	14:56 (24 HR)
Vital Signs Date and Time (derived)	07 OCT 2020 14:56
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	96 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3732304

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Feb 2021 01:40:45

Generated On: 10 Jun 2021 09:26:54

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

07 OCT 2020

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

US3732304

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 26 Feb 2021 01:40:45

Generated On: 10 Jun 2021 09:26:54

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	07 OCT 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3732304

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 26 Feb 2021 01:40:45

Generated On: 10 Jun 2021 09:26:54

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) 07 OCT 2020

What was the treatment time? (00:00-23:59) 14:26 (24 HR)

Treatment Date and Time (derived) 07 OCT 2020 14:26

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



US3732304

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Feb 2021 01:40:45

Generated On: 10 Jun 2021 09:26:54

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

07 OCT 2020

Collection time (00:00-23:59)

14:20 (24 HR)

Collection date and time (derived)

07 OCT 2020 14:20

US3732304

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Feb 2021 01:40:45

Generated On: 10 Jun 2021 09:26:54

Collection date (dd MMM yyyy)			07 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:58	07 OCT 2020 13:58
Nasopharyngeal Swab 2	No		

US3732304

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 01:40:45

Generated On: 10 Jun 2021 09:26:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:26:54

**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

98.7 °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

07 OCT 2020 15:00

PC Open Date & Time

07 OCT 2020 14:46

PC Close Date & Time

07 OCT 2020 17:16

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:26:54

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.1 °F

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

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

PC Time Stamp	08 OCT 2020 11:01
PC Open Date & Time	07 OCT 2020 18:11
PC Close Date & Time	08 OCT 2020 11:59

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:26:54

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °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

08 OCT 2020 19:31

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:26:54

**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

99.1 °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

09 OCT 2020 19:46

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:26:54

**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

99.2 °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

10 OCT 2020 19:03

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59



US3732304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:26:54

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °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

12 OCT 2020 01:42

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:26:54

**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

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

Yes ☐

No ☐

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

To **TREAT** pain or fever that has already occurred

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:26:54

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 OCT 2020 13:18

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:26:54

**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

07 OCT 2020 15:01

PC Open Date & Time

07 OCT 2020 14:46

PC Close Date & Time

07 OCT 2020 17:16

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:26:54

**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

08 OCT 2020 11:01

PC Open Date & Time

07 OCT 2020 18:11

PC Close Date & Time

08 OCT 2020 11:59

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:26:54

**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

08 OCT 2020 19:32

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:26:54

**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

10 OCT 2020 00:00

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:26:54

**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

10 OCT 2020 19:03

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59



US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:26:54

**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

12 OCT 2020 01:42

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:26:54

**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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:26:54

**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

13 OCT 2020 13:18

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3732304

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:26:54

**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 ☐

US3732304

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:26:54

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

No ☒

Yes ☐

PC Time stamp	07 OCT 2020 15:01
PC Open Date & Time	07 OCT 2020 14:46
PC Close Date & Time	07 OCT 2020 17:16

US3732304

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:26:54

**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 ☐

US3732304

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:26:54

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

No ☒

Yes ☐

PC Time stamp	08 OCT 2020 11:02
PC Open Date & Time	07 OCT 2020 18:11
PC Close Date & Time	08 OCT 2020 11:59

US3732304

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:26:54

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

111 of 2634



US3732304

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:26:54

Yes <input type="checkbox"/>	
PC Time stamp	08 OCT 2020 19:32
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3732304

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:26:54

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

113 of 2634

US3732304

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:26:54

Yes <input type="checkbox"/>	
PC Time stamp	10 OCT 2020 00:00
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3732304

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:26:54

**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 ☒

US3732304

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:26:54

Yes <input type="checkbox"/>	
PC Time stamp	10 OCT 2020 19:03
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3732304

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:26:54

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3732304

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:26:54

Yes <input type="checkbox"/>	
PC Time stamp	12 OCT 2020 01:43
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3732304

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:26:54

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 ☐



US3732304

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:26:54

Yes ☐

PC Time stamp

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3732304

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:26:54

**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)

121 of 2634

US3732304

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:26:54

Yes <input type="checkbox"/>	
PC Time stamp	13 OCT 2020 13:19
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Pain\_Day(8)

Generated On: 10 Jun 2021 09:26:54

**TIMEPOINT**

DAY 8

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 ☐

PC Time Stamp 14 OCT 2020 23:07

PC Open Date & Time 14 OCT 2020 12:00

PC Close Date & Time 15 OCT 2020 11:59

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Pain\_Day(9)

Generated On: 10 Jun 2021 09:26:54

**TIMEPOINT**

DAY 9

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 ☐

PC Time Stamp

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Pain\_Day(10)

Generated On: 10 Jun 2021 09:26:54

---

**TIMEPOINT**

DAY 10

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 ☐

---

PC Time Stamp

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

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US3732304

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 09:26:54

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	14 OCT 2020 23:08
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3732304

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 09:26:54

<b>TIMEPOINT</b>	DAY 9
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59



US3732304

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(10)

Generated On: 10 Jun 2021 09:26:54

<b>TIMEPOINT</b>	DAY 10
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3732304

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 01:40:37

Generated On: 10 Jun 2021 09:26:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3732304

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 01:40:37

Generated On: 10 Jun 2021 09:26:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732304

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 01:40:37

Generated On: 10 Jun 2021 09:26:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3732304

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 01:40:37

Generated On: 10 Jun 2021 09:26:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732304

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 01:40:37

Generated On: 10 Jun 2021 09:26:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3732304

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 01:40:37

Generated On: 10 Jun 2021 09:26:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732304

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 01:40:45

Generated On: 10 Jun 2021 09:26:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	03 DEC 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



US3732304

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Feb 2021 01:40:45

Generated On: 10 Jun 2021 09:26:54

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	03 DEC 2020
Time of assessment (00:00-23:59)	13:40 (24 HR)
Vital Signs Date and Time (derived)	03 DEC 2020 13:40
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	89 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	101 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3732304

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Feb 2021 01:40:45

Generated On: 10 Jun 2021 09:26:54

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

03 DEC 2020

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

US3732304

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Feb 2021 01:40:45

Generated On: 10 Jun 2021 09:26:54

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	03 DEC 2020
Collection time (00:00-23:59)	14:35 (24 HR)
Collection date and time (derived)	03 DEC 2020 14:35

US3732304

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 01:40:45

Generated On: 10 Jun 2021 09:26:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

Patient Cloud Close Date & Time

13 NOV 2020 23:59

US3732304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

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 <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"/>

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

Patient Cloud Close Date & Time

20 NOV 2020 23:59



US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

TIMEPOINT	DAY 75
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"/>

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

20 NOV 2020 00:01

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[Patient Cloud Close Date & Time](#)

24 NOV 2020 23:59

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

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 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"/>

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

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[Patient Cloud Open Date & Time](#)

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27 NOV 2020 00:01

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[Patient Cloud Close Date & Time](#)

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01 DEC 2020 23:59

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 DEC 2020 00:01

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[Patient Cloud Close Date & Time](#)

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08 DEC 2020 23:59

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

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

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 DEC 2020 23:59



US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

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

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

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[Patient Cloud Open Date & Time](#)

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18 DEC 2020 00:01

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[Patient Cloud Close Date & Time](#)

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22 DEC 2020 23:59

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 DEC 2020 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 DEC 2020 23:59
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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

**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

05 JAN 2021 14:31:58

Patient Cloud Open Date & Time

01 JAN 2021 00:01

Patient Cloud Close Date & Time

05 JAN 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

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[Patient Cloud Open Date & Time](#)

08 JAN 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 JAN 2021 23:59

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	16 JAN 2021 07:20:22
Patient Cloud Open Date & Time	15 JAN 2021 00:01
Patient Cloud Close Date & Time	19 JAN 2021 23:59



US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

**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

25 JAN 2021 21:57:15

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

**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

31 JAN 2021 10:42:24

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

**TIMEPOINT**

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 FEB 2021 16:39:34

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

**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

12 FEB 2021 09:56:38

Patient Cloud Open Date & Time

12 FEB 2021 00:01

Patient Cloud Close Date & Time

16 FEB 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

**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

19 FEB 2021 15:57:36

Patient Cloud Open Date & Time

19 FEB 2021 00:01

Patient Cloud Close Date & Time

23 FEB 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

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

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

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[Patient Cloud Close Date & Time](#)

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02 MAR 2021 23:59

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

**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

05 MAR 2021 13:05:09

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59



US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

**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

16 MAR 2021 16:58:43

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

**TIMEPOINT**

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 MAR 2021 17:32:23

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

**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

26 MAR 2021 17:49:51

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

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

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

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[Patient Cloud Open Date & Time](#)

02 APR 2021 00:01

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[Patient Cloud Close Date & Time](#)

06 APR 2021 23:59

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

**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

12 APR 2021 03:47:12

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

**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

16 APR 2021 20:06:43

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>



**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	23 APR 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	27 APR 2021 23:59
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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

**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

01 MAY 2021 20:39:09

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

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[Patient Cloud Open Date & Time](#)

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07 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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11 MAY 2021 23:59

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

**TIMEPOINT**

DAY 250

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

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

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

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

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[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

**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 ☐

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

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[Patient Cloud Open Date & Time](#)

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21 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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25 MAY 2021 23:59

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

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="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"/>

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

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[Patient Cloud Open Date & Time](#)

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28 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 JUN 2021 23:59

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

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"/>

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

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[Patient Cloud Open Date & Time](#)

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04 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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08 JUN 2021 23:59

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

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 <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"/>

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

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[Patient Cloud Open Date & Time](#)

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11 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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15 JUN 2021 23:59

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

**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 ☐  
Yes ☐

Have you been exposed to someone with known SARS-CoV-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 ☐

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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



US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

**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 ☐

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

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[Patient Cloud Open Date & Time](#)

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25 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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29 JUN 2021 23:59

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

**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 ☐

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

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[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

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

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

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 <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"/>

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 JUL 2021 23:59



US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

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

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

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[Patient Cloud Close Date & Time](#)

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27 JUL 2021 23:59

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

**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°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 ☐

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

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[Patient Cloud Open Date & Time](#)

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30 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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03 AUG 2021 23:59

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

**TIMEPOINT**

DAY 334

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

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

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

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

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

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

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

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

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

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[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

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="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"/>

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	13 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	17 AUG 2021 23:59
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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

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"/>

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

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[Patient Cloud Close Date & Time](#)

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24 AUG 2021 23:59

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

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[Patient Cloud Open Date & Time](#)

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27 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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31 AUG 2021 23:59

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

**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 ☐

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59



US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

**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 ☐

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

**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 ☐

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

24 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

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"/>

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

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

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

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

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[Patient Cloud Open Date & Time](#)

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08 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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12 OCT 2021 23:59

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

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"/>

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

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"/>

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

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"/>

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

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[Patient Cloud Close Date & Time](#)

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02 NOV 2021 23:59

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

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"/>

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

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[Patient Cloud Close Date & Time](#)

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09 NOV 2021 23:59

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

**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 ☐

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 NOV 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	16 NOV 2021 23:59
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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

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="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"/>

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

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"/>

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

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

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

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[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

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"/>

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 DEC 2021 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

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="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"/>

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

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[Patient Cloud Close Date & Time](#)

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21 DEC 2021 23:59

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

**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 ☐

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

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

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

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[Patient Cloud Open Date & Time](#)

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31 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 JAN 2022 23:59

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

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

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

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[Patient Cloud Open Date & Time](#)

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07 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 JAN 2022 23:59

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

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"/>

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

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[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

**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 ☐

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

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[Patient Cloud Close Date & Time](#)

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25 JAN 2022 23:59

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

TIMEPOINT	DAY 509
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

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[Patient Cloud Close Date & Time](#)

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01 FEB 2022 23:59

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

**TIMEPOINT**

DAY 516

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

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

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

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

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

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

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

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

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

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[Patient Cloud Close Date & Time](#)

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08 FEB 2022 23:59

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

**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 ☐

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

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[Patient Cloud Open Date & Time](#)

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11 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 FEB 2022 23:59

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

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="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"/>

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

**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°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 ☐

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

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[Patient Cloud Close Date & Time](#)

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01 MAR 2022 23:59

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

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="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"/>

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

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[Patient Cloud Close Date & Time](#)

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08 MAR 2022 23:59

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

**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 ☐

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

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[Patient Cloud Open Date & Time](#)

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11 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 MAR 2022 23:59

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

**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 ☐

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

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[Patient Cloud Close Date & Time](#)

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22 MAR 2022 23:59

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

**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 ☐

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

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[Patient Cloud Close Date & Time](#)

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29 MAR 2022 23:59

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

**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 ☐

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

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[Patient Cloud Close Date & Time](#)

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05 APR 2022 23:59

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

**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 ☐

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

**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 ☐

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

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[Patient Cloud Open Date & Time](#)

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15 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 APR 2022 23:59

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

**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 ☐

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	22 APR 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	26 APR 2022 23:59
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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

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

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

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[Patient Cloud Close Date & Time](#)

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03 MAY 2022 23:59

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

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

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

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[Patient Cloud Close Date & Time](#)

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10 MAY 2022 23:59

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

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="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"/>

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

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[Patient Cloud Close Date & Time](#)

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17 MAY 2022 23:59

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

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

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59



US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

**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 ☐

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

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[Patient Cloud Close Date & Time](#)

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31 MAY 2022 23:59

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

**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 ☐

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

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[Patient Cloud Close Date & Time](#)

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07 JUN 2022 23:59

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

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[Patient Cloud Close Date & Time](#)

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14 JUN 2022 23:59

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

**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 ☐

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

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[Patient Cloud Close Date & Time](#)

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21 JUN 2022 23:59

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

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[Patient Cloud Close Date & Time](#)

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28 JUN 2022 23:59

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

**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 ☐

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

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[Patient Cloud Close Date & Time](#)

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05 JUL 2022 23:59

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

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="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"/>

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

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[Patient Cloud Open Date & Time](#)

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08 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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12 JUL 2022 23:59

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

**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 ☐

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

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[Patient Cloud Open Date & Time](#)

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15 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 JUL 2022 23:59

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

**TIMEPOINT**

DAY 684

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

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

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

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

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

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

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

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

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	22 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 JUL 2022 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

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[Patient Cloud Close Date & Time](#)

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02 AUG 2022 23:59

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

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[Patient Cloud Close Date & Time](#)

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09 AUG 2022 23:59

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

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

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	16 AUG 2022 23:59
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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

**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 ☐

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

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"/>

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	30 AUG 2022 23:59
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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

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"/>

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

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[Patient Cloud Close Date & Time](#)

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06 SEP 2022 23:59

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

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="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"/>

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

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[Patient Cloud Open Date & Time](#)

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09 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 SEP 2022 23:59

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 SEP 2022 23:59

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

**TIMEPOINT**

DAY 747

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

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

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

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

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

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

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

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

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

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[Patient Cloud Close Date & Time](#)

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27 SEP 2022 23:59

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

**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 ☐

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

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[Patient Cloud Close Date & Time](#)

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04 OCT 2022 23:59

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

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

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59



US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

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"/>

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

**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 ☐

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

**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 ☐

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

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[Patient Cloud Close Date & Time](#)

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01 NOV 2022 23:59

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

**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 ☐

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

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[Patient Cloud Close Date & Time](#)

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08 NOV 2022 23:59

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US3732304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:26:54

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"/>

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

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[Patient Cloud Open Date & Time](#)

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11 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 NOV 2022 23:59

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**US3732304**

**Folder: Cosmetic Injections and Dermal Fillers**

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

**Generated On: 10 Jun 2021 09:26:54**

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		05 MAR 2021 13:05:17

US3732304

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 01:40:37

Generated On: 10 Jun 2021 09:26:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3732304

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 01:40:37

Generated On: 10 Jun 2021 09:26:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732304

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 01:40:37

Generated On: 10 Jun 2021 09:26:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3732304

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 01:40:37

Generated On: 10 Jun 2021 09:26:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732304

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 01:40:37

Generated On: 10 Jun 2021 09:26:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3732304

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 01:40:37

Generated On: 10 Jun 2021 09:26:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732304

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 21:41:43

Generated On: 10 Jun 2021 09:26:54

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 05 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3732304

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 21:41:43

Generated On: 10 Jun 2021 09:26:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732304

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 22:23:32

Generated On: 10 Jun 2021 09:26:54

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

Visit date (dd MMM yyyy)	15 APR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3732304

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 22:23:32

Generated On: 10 Jun 2021 09:26:54

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 APR 2021
Time of assessment (00:00-23:59)	11:02 (24 HR)
Vital Signs Date and Time (derived)	15 APR 2021 11:02
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	116 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	99 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3732304

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 22:23:32

Generated On: 10 Jun 2021 09:26:54

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.*

US3732304

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 22:23:32

Generated On: 10 Jun 2021 09:26:54

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

Collection date (dd MMM yyyy)	15 APR 2021
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Collection time (00:00-23:59)	11:14 (24 HR)
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Collection date and time (derived)	15 APR 2021 11:14
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US3732304

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 22:23:32

Generated On: 10 Jun 2021 09:26:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



**US3732304**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:26:54**

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*

**US3732304**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:26:54**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**US3732304**

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

**Form: COVID-19 Contact**

**Generated On: 10 Jun 2021 09:26:54**

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

**US3732304**

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

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

**Generated On: 10 Jun 2021 09:26:54**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

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US3732304

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

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 01:40:37

Generated On: 10 Jun 2021 09:26:54

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

Visit date (dd MMM yyyy)	05 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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US3732304

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

Form: Unblinding

Data signed: (b) (4) 09 Apr 2021 21:41:43

Generated On: 10 Jun 2021 09:26:54

Date of updated informed consent ( <i>dd MMM yyyy</i> )	05 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> )	05 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

US3732304

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 26 Feb 2021 01:40:37

Generated On: 10 Jun 2021 09:26:54

Height	
Weight	
BMI (xxx.x)	

US3732304

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Feb 2021 01:40:37

Generated On: 10 Jun 2021 09:26:54

Height	
Weight	
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)	05 FEB 2021
Time of assessment (00:00-23:59)	11:44 (24 HR)
Vital Signs Date and Time (derived)	05 FEB 2021 11:44
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG



US3732304

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Feb 2021 01:40:37

Generated On: 10 Jun 2021 09:26:54

Height	
Weight	
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)	05 FEB 2021
Time of assessment (00:00-23:59)	13:01 (24 HR)
Vital Signs Date and Time (derived)	05 FEB 2021 13:01
Temperature (xxx.x)	99.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3732304

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

Form: Physical Examination

Data signed: (b) (4) 26 Feb 2021 01:40:37

Generated On: 10 Jun 2021 09:26:54

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

05 FEB 2021

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

US3732304

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

Form: Pregnancy Test

Data signed: (b) (4) 26 Feb 2021 01:40:37

Generated On: 10 Jun 2021 09:26:54

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	05 FEB 2021
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	05 FEB 2021
Collection time	11:50
Collection date and time (derived)	05 FEB 2021 11:50

US3732304

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

Form: Exposure

Data signed: (b) (4) 26 Feb 2021 01:40:37

Generated On: 10 Jun 2021 09:26:54

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) 05 FEB 2021

What was the treatment time? (00:00-23:59) 12:28 (24 HR)

Treatment Date and Time (derived) 05 FEB 2021 12:28

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

US3732304

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Feb 2021 01:40:37

Generated On: 10 Jun 2021 09:26:54

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

05 FEB 2021

Collection time (00:00-23:59)

11:00 (24 HR)

Collection date and time (derived)

05 FEB 2021 11:00

US3732304

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 26 Feb 2021 01:40:37

Generated On: 10 Jun 2021 09:26:54

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	05 FEB 2021
Collection time (00:00 - 23:59)	11:09
Collection Date and Time (derived)	05 FEB 2021 11:09

US3732304

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

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 01:40:37

Generated On: 10 Jun 2021 09:26:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732304

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 01:40:38

Generated On: 10 Jun 2021 09:26:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3732304

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 01:40:38

Generated On: 10 Jun 2021 09:26:54

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

US3732304

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 21:41:43

Generated On: 10 Jun 2021 09:26:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	05 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

US3732304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 09 Apr 2021 21:41:43

Generated On: 10 Jun 2021 09:26:54

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)	05 MAR 2021
Time of assessment (00:00-23:59)	12:43 (24 HR)
Vital Signs Date and Time (derived)	05 MAR 2021 12:43
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	89 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3732304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 09 Apr 2021 21:41:43

Generated On: 10 Jun 2021 09:26:54

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)	05 MAR 2021
Time of assessment (00:00-23:59)	14:09 (24 HR)
Vital Signs Date and Time (derived)	05 MAR 2021 14:09
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)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3732304

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 21:41:43

Generated On: 10 Jun 2021 09:26:54

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

05 MAR 2021

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

US3732304

Folder: OL-D29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 09 Apr 2021 21:41:43

Generated On: 10 Jun 2021 09:26:54

Was the pregnancy test performed? Yes ☒  
No ☐

Date of test (dd MMM yyyy) 05 MAR 2021

Test performed Urine ☒  
Serum ☐

Result Positive ☐  
Negative ☒

Was FSH sample collected? Yes ☐  
No ☒

Collection date \_\_\_\_\_  
Collection time \_\_\_\_\_  
Collection date and time (derived) \_\_\_\_\_

US3732304

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 09 Apr 2021 21:41:43

Generated On: 10 Jun 2021 09:26:54

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) 05 MAR 2021

What was the treatment time? (00:00-23:59) 13:35 (24 HR)

Treatment Date and Time (derived) 05 MAR 2021 13:35

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

US3732304

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 21:41:43

Generated On: 10 Jun 2021 09:26:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3732304

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 21:41:43

Generated On: 10 Jun 2021 09:26:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3732304

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 21:41:43

Generated On: 10 Jun 2021 09:26:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732304

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 22:23:32

Generated On: 10 Jun 2021 09:26:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 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

US3732304

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 22:23:32

Generated On: 10 Jun 2021 09:26:54

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	15 APR 2021
Time of assessment ( <i>00:00-23:59</i> )	11:02 (24 HR)
Vital Signs Date and Time (derived)	15 APR 2021 11:02
Temperature ( <i>xxx.x</i> )	98.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	116 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	99 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	68 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3732304

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 22:23:32

Generated On: 10 Jun 2021 09:26:54

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 APR 2021

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

US3732304

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 22:23:03

Generated On: 10 Jun 2021 09:26:54

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	15 APR 2021
Collection time (00:00-23:59)	11:14 (24 HR)
Collection date and time (derived)	15 APR 2021 11:14

US3732304

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 26 Feb 2021 01:40:36

Generated On: 10 Jun 2021 09:26:54

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Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

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US3732304

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 22:23:02

Generated On: 10 Jun 2021 09:26:54

AEID

Adverse event

PAIN AT INJECTION SITE

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)

08 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)

18 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

PRODUCTION RELEASE (v12.003

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EAB) (1725)



US3732304

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 22:23:02

Generated On: 10 Jun 2021 09:26:54

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

US3732304

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 22:23:02

Generated On: 10 Jun 2021 09:26:54

AEID	USA-US102-2020-MRNA-1273-P30 1000004
Adverse event	BILATERAL PULMONARY EMBOLISM
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 checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	25 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	15 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input 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 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	05 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
PRODUCTION RELEASE (v12.003 EAB) (1725)	385 of 2634

US3732304

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 22:23:02

Generated On: 10 Jun 2021 09:26:54

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 checked="" type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	SHORTNESS OF BREATH OR EXERTION WHEN BENDING DOWN
Narrative	

US3732304

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 22:23:02

Generated On: 10 Jun 2021 09:26:54

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SUBJECT CALLED SITE TO  
REPORT ABOVE AE AND  
HOSPITALIZATION FROM  
10/29/20 - ONGOING. SUBJECT IS  
ADMITTED AT UCSD, MEDICAL  
RECORDS WILL BE REQUESTED  
UPON SUBJECT'S RETURN TO  
SITE. SUBJECT DENIED ANY  
RECENT TRAVEL, SMOKER OR  
ORAL BC. SUBJECT REPORTED  
TWO NEGATIVE TESTS FOR  
COVID, PERFORMED IN  
HOSPITAL. PER SUBJECT,  
UNKNOWN CAUSE AT THIS  
TIME. SUBJECT STATED IT WAS  
99% OCCLUDED.

09APR2021 MR NARRATIVE  
UPDATES: NEGATIVE COVID-19  
NASAL SWAB COLLECTED ON  
30OCT2020 @ 0009. DIAGNOSTIC  
TESTS INCLUDE CHEST X-RAYS  
(29OCT2020 & 02NOV2020), CTA  
PULMONARY EMBOLUS  
(29OCT2020), AND  
ULTRASOUND LOWER  
EXTREMITIES VENOUS DUPLEX  
BILATERAL (30OCT2020).  
29OCT2020 CHEST X-RAY  
REPORTS BRONCHIAL WALL  
THICKENING AND NO  
EVIDENCE OF PNEUMONIA  
WHILE 02NOV2020 CHEST  
X-RAY SHOWS STREAKY  
BIBASAL OPACITIES

US3732304

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 22:23:02

Generated On: 10 Jun 2021 09:26:54

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(ATELECTASIS OR EVOLVING  
INFARCTS). CTA PULMONARY  
EMBOLUS REVEALED  
EXTENSIVE NONOCCLUSIVE  
BILATERAL PULMONARY  
EMBOLI WITHIN LOBAR AND  
SEGMENTAL PULMONARY  
ARTERIES (PROBABLE RIGHT  
HEART STRAIN). LOWER  
EXTREMITY ULTRASOUND  
SHOWED NO EVIDENCE OF  
DVTs. D-DIMER COLLECTED  
TWICE ON 29OCT2020: @ 1856:  
3599 NG/ML (REFERENCE  
RANGE <241 NG/ML) AND @  
1935: 4487 NG/ML. DISCHARGE  
SUMMARY REPORTS NO CLEAR  
PROVOKING FACTOR FOR PE.  
NOTE SUBJECT HAD REPORTED  
99% OCCLUSION BUT MR CTA  
REPORTS PES WERE  
NON-OCCLUSIVE.

---

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

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US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 26 Feb 2021 01:40:37

Generated On: 10 Jun 2021 09:26:54

---

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

Yes ☒

No ☐

---

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 21:41:43

Generated On: 10 Jun 2021 09:26:54

Name of Medication ZYRTEC

Prophylaxis Yes ☐  
No ☒

Indication PET DANDER AND  
ENVIRONMENTAL ALLERGIES

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 21:41:43

Generated On: 10 Jun 2021 09:26:54

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 1978	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 21:41:43

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Name of Medication ALBUTEROL

Prophylaxis Yes ☐  
No ☒

Indication ASTHMA

Dose per administration 90

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 21:41:43

Generated On: 10 Jun 2021 09:26:54

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 1974	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 21:41:43

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Name of Medication PANTOPRAZOLE

Prophylaxis Yes ☐  
No ☒

Indication GASTROESOPHAGEAL REFLUX  
DISEASE

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 21:41:43

Generated On: 10 Jun 2021 09:26:54

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 1998	
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) 09 Apr 2021 21:41:43

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Name of Medication GABAPENTIN

Prophylaxis Yes ☐  
No ☒

Indication CHRONIC BACK PAIN

Dose per administration 1200

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) 09 Apr 2021 21:41:43

Generated On: 10 Jun 2021 09:26:54

	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 (5)

Data signed: (b) (4) 09 Apr 2021 21:41:43

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Name of Medication NORCO

Prophylaxis Yes ☐  
No ☒

Indication POST SURGICAL PAIN

Dose per administration 10/325

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) 09 Apr 2021 21:41:43

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



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

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Name of Medication ESTRADIOL 0.01% CREAM

Prophylaxis Yes ☐  
No ☒

Indication PERI-MENOPAUSE

Dose per administration 1

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

If dose unit is Other, specify PUMP

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) 09 Apr 2021 21:41:43

Generated On: 10 Jun 2021 09:26:54

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	2	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Apr 2021 21:41:43

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Name of Medication NUVA RING

Prophylaxis Yes ☒  
No ☐

Indication PREGNANCY

Dose per administration 1

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

If dose unit is Other, specify RING

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Apr 2021 21:41:43

Generated On: 10 Jun 2021 09:26:54

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input checked="" 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 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	11 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input checked="" 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 (8)

Data signed: (b) (4) 09 Apr 2021 21:41:43

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Name of Medication AMITRIPTYLINE

Prophylaxis Yes ☐  
No ☒

Indication DEPRESSION / INSOMNIA

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 09 Apr 2021 21:41:43

Generated On: 10 Jun 2021 09:26:54

	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 1996
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Apr 2021 21:41:43

Generated On: 10 Jun 2021 09:26:54

Name of Medication FLUOXETINE

Prophylaxis Yes ☐  
No ☒

Indication DEPRESSION

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Apr 2021 21:41:43

Generated On: 10 Jun 2021 09:26:54

	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 1996
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 09 Apr 2021 21:41:43

Generated On: 10 Jun 2021 09:26:54

Name of Medication WELLBUTRIN

Prophylaxis Yes ☐  
No ☒

Indication DEPRESSION

Dose per administration 450

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 09 Apr 2021 21:41:43

Generated On: 10 Jun 2021 09:26:54

	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 1996
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 09 Apr 2021 21:41:43

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Name of Medication MAGNESIUM

Prophylaxis Yes ☒  
No ☐

Indication VITAMIN DEFICIENCY

Dose per administration 160

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 09 Apr 2021 21:41:43

Generated On: 10 Jun 2021 09:26:54

	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 1998
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"/>

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 09 Apr 2021 21:41:43

Generated On: 10 Jun 2021 09:26:54

Name of Medication MULTIVITAMIN

Prophylaxis Yes ☒  
No ☐

Indication VITAMIN DEFICIENCY

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 09 Apr 2021 21:41:43

Generated On: 10 Jun 2021 09:26:54

	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 1998
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"/>

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 09 Apr 2021 21:41:43

Generated On: 10 Jun 2021 09:26:54

Name of Medication VITAMIN D3

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 09 Apr 2021 21:41:43

Generated On: 10 Jun 2021 09:26:54

	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 1998
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"/>



US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 09 Apr 2021 21:41:43

Generated On: 10 Jun 2021 09:26:54

Name of Medication ZINC

Prophylaxis Yes ☒  
No ☐

Indication VITAMIN DEFICIENCY

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 09 Apr 2021 21:41:43

Generated On: 10 Jun 2021 09:26:54

	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 1998
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"/>

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 09 Apr 2021 21:41:43

Generated On: 10 Jun 2021 09:26:54

Name of Medication HEPARIN

Prophylaxis Yes ☐  
No ☒

Indication BILATERAL PULMONARY EMBOLISM

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

DRIP

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 09 Apr 2021 21:41:43

Generated On: 10 Jun 2021 09:26:54

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input checked="" type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		03 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 09 Apr 2021 21:41:43

Generated On: 10 Jun 2021 09:26:54

Name of Medication ELOQUIS

Prophylaxis Yes ☐  
No ☒

Indication SAE- BILATERAL PULMONARY EMBOLISM

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 09 Apr 2021 21:41:43

Generated On: 10 Jun 2021 09:26:54

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		03 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 09 Apr 2021 21:41:43

Generated On: 10 Jun 2021 09:26:54

Name of Medication NAPROXEN

Prophylaxis Yes ☐  
No ☒

Indication CHRONIC BACK PAIN

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 09 Apr 2021 21:41:43

Generated On: 10 Jun 2021 09:26:54

	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 type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	29 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>



US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 09 Apr 2021 21:41:43

Generated On: 10 Jun 2021 09:26:54

Name of Medication CYCLOBENZAPRINE

Prophylaxis Yes ☐  
No ☒

Indication CHRONIC BACK PAIN

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 09 Apr 2021 21:41:43

Generated On: 10 Jun 2021 09:26:54

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		22 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3732304

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 09 Apr 2021 21:41:43

Generated On: 10 Jun 2021 09:26:54

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3732304

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 09 Apr 2021 21:41:43

Generated On: 10 Jun 2021 09:26:54

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
29 OCT 2020	CHEST X-RAY	Diagnostic	
29 OCT 2020	CTA PULMONARY EMBOLUS	Diagnostic	
30 OCT 2020	BILATERAL VENOUS DUPLEX LOWER EXTREMITY ULTRASOUND	Diagnostic	
02 NOV 2020	CHEST X-RAY	Diagnostic	

US3732304

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:26:54

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

US3732304

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:26:54

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 ☐

US3732304

Folder: SAE USA-US102-2020-MRNA-1273-P301000004

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 22:23:32

Generated On: 10 Jun 2021 09:26:54

SAEID	USA-US102-2020-MRNA-1273-P301000004
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)	8

US3732304

Folder: SAE USA-US102-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 22:23:32

Generated On: 10 Jun 2021 09:26:54

SAEID	USA-US102-2020-MRNA-1273-P301000004
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)	8
Date of submission (Pre-filled from custom function)	04/NOV/2020 16:38
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



US3732304

Folder: SAE USA-US102-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 22:23:32

Generated On: 10 Jun 2021 09:26:54

SAEID	USA-US102-2020-MRNA-1273-P301000004
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)	8
Date of submission (Pre-filled from custom function)	25/NOV/2020 14:18
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.	True

US3732304

Folder: SAE USA-US102-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Data signed: (b) (4) 28 Apr 2021 22:23:32

Generated On: 10 Jun 2021 09:26:54

SAEID	USA-US102-2020-MRNA-1273-P301000004
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)	8
Date of submission (Pre-filled from custom function)	17/FEB/2021 11:11
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

US3732304

Folder: SAE USA-US102-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Data signed: (b) (4) 28 Apr 2021 22:23:32

Generated On: 10 Jun 2021 09:26:54

SAEID	USA-US102-2020-MRNA-1273-P301000004
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)	8
Date of submission (Pre-filled from custom function)	12/APR/2021 09:28
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

US3732304

Folder: SAE USA-US102-2020-MRNA-1273-P301000004

Form: Safety Report Form (5)

Data signed: (b) (4) 28 Apr 2021 22:23:32

Generated On: 10 Jun 2021 09:26:54

SAEID	USA-US102-2020-MRNA-1273-P301000004
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)	8
Date of submission (Pre-filled from custom function)	16/APR/2021 05:55
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

US3732304

Folder: SAE USA-US102-2020-MRNA-1273-P301000004

Form: Safety Report Form (6)

Data signed: (b) (4) 28 Apr 2021 22:23:32

Generated On: 10 Jun 2021 09:26:54

SAEID	USA-US102-2020-MRNA-1273-P301000004
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)	8
Date of submission (Pre-filled from custom function)	20/APR/2021 06:57
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

US3732304

Folder: SAE USA-US102-2020-MRNA-1273-P301000004

Form: Safety Report Form (7)

Data signed: (b) (4) 28 Apr 2021 22:23:32

Generated On: 10 Jun 2021 09:26:54

SAEID	USA-US102-2020-MRNA-1273-P301000004
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)	8
Date of submission (Pre-filled from custom function)	21/APR/2021 13:34
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

US3732304

Folder: SAE USA-US102-2020-MRNA-1273-P301000004

Form: Safety Report Form (8)

Data signed: (b) (4) 28 Apr 2021 22:23:32

Generated On: 10 Jun 2021 09:26:54

SAEID	USA-US102-2020-MRNA-1273-P301000004
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)	8
Date of submission (Pre-filled from custom function)	26/APR/2021 12:49
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

US3732304 (Prod: eStudySite - La Mesa - PPDS)



**US3732304**

**Form: Participant Creation**

**Generated On: 10 Jun 2021 09:26:54**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:29:44
User entered 'US3732304'	RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 21:39:21

**US3732304**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:26:54**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:32:53
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:36:32

**US3732304**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 21:32:53
User entered '09 SEP 2020'	RWS_ENDPOINT	09 Sep 2020 21:39:22
	ENDPOINT (b) (4)	

**US3732304**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:26:54**

[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 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:32:53
User entered 'Clinic (Clinic)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:36:32

**US3732304**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:26:54**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered 'SCRN'	System	10 Sep 2020 17:36:32

**US3732304**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:33:29
User entered (b) (6) 1964'	RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 21:39:23

**US3732304**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:26:54**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:33:29
User entered '55'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:42:13

**US3732304**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:26:54**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered 'YEARS'	System	10 Sep 2020 17:42:13



**US3732304**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:26:54**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered '56'	System	09 Sep 2020 23:12:52

**US3732304**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:26:54**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:33:29
User entered 'Female (F)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:42:13

**US3732304**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:26:54**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:33:29
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:42:13

**US3732304**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:26:54**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:33:29
User entered 'l'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:42:13

**US3732304**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:26:54**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:33:29
User entered 'l'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:42:13

**US3732304**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:26:54**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:33:29
User entered '0'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:42:13

**US3732304**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:26:54**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:33:29
User entered '0'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:42:13

**US3732304**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:26:54**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:33:29
User entered '0'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:42:13



**US3732304**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:26:54**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:33:29
User entered '0'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:42:13

**US3732304**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:26:54**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:33:29
User entered empty.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:42:13

**US3732304**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:26:54**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:33:29
User entered '0'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:42:13

**US3732304**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:26:54**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:33:29
User entered '0'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:42:13

**US3732304**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:26:54**

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:33:37
User entered '09 Sep 2020'	Lauren Arnett (b) (4) (b) (4)	09 Sep 2020 23:12:52

**US3732304**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered 'Sep 2020'	System	09 Sep 2020 23:12:52

**US3732304**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered '2020'	System	09 Sep 2020 23:12:52

**US3732304**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:26:54**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:33:37
User entered 'Amendment 3 (3)'	Lauren Arnett (b) (4) (b) (4)	09 Sep 2020 23:12:52



**US3732304**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:33:37
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	09 Sep 2020 23:12:52

**US3732304**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:26:54**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:33:37
User entered empty.	Lauren Arnett (b) (4) (b) (4)	09 Sep 2020 23:12:52

**US3732304**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:26:54**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:33:37
User entered empty.	Lauren Arnett (b) (4) (b) (4)	09 Sep 2020 23:12:52

**US3732304**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:26:54**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:33:37
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	09 Sep 2020 23:12:52

**US3732304**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:26:54**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:33:37
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 21:39:22

**US3732304**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:26:54**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered 'I'	System	09 Sep 2020 23:12:58

**US3732304**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:33:44
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	09 Sep 2020 23:12:58

**US3732304**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 10 Jun 2021 09:26:54**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:33:51
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:42:34



US3732304

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:26:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergic conditions NEC, PT: Hypersensitivity, LLT: Environmental allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 17:43:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 17:43:45
Data point term sent to Coder	System	10 Sep 2020 17:43:16
User entered 'environmental allergies'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:42:54

**US3732304**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered 'un UNK 1965'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:42:54

**US3732304**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '0'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:42:54

**US3732304**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:42:54

**US3732304**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:26:54**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered empty.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:42:54

**US3732304**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '0'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:42:54

**US3732304**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered 'Jan 1965'	System	10 Sep 2020 17:42:54

**US3732304**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered '1965'	System	10 Sep 2020 17:42:54



**US3732304**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered empty.	System	10 Sep 2020 17:42:54

**US3732304**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered empty.	System	10 Sep 2020 17:42:54

US3732304

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:26:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergic conditions NEC, PT: Allergy to animal, LLT: Allergy to animal dander - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 17:43:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 17:43:45
Data point term sent to Coder	System	10 Sep 2020 17:43:17
User entered 'allergy to pet dander'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:43:06

**US3732304**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered 'un UNK 1978'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:43:06

**US3732304**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '0'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:43:06

**US3732304**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:43:06

**US3732304**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:26:54**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered empty.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:43:06

**US3732304**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '0'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:43:06



**US3732304**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered 'Jan 1978'	System	10 Sep 2020 17:43:06

**US3732304**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered '1978'	System	10 Sep 2020 17:43:06

**US3732304**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered empty.	System	10 Sep 2020 17:43:06

**US3732304**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered empty.	System	10 Sep 2020 17:43:06

US3732304

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:26:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 17:45:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 17:45:46
Data point term sent to Coder	System	10 Sep 2020 17:44:18
User entered 'asthma'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:43:24

**US3732304**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered 'un UNK 1974'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:43:24

**US3732304**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:26:54**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '0'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:43:24

**US3732304**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:26:54**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:43:24



**US3732304**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:26:54**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered empty.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:43:24

**US3732304**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:26:54**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '0'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:43:24

**US3732304**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered 'Jan 1974'	System	10 Sep 2020 17:43:24

**US3732304**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered '1974'	System	10 Sep 2020 17:43:24

**US3732304**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered empty.	System	10 Sep 2020 17:43:24

**US3732304**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered empty.	System	10 Sep 2020 17:43:24

US3732304

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:26:54

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 17:46:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 17:46:49
Data point term sent to Coder	System	10 Sep 2020 17:45:23
User entered 'gastroesophageal reflux disease'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:44:37

**US3732304**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered 'un UNK 1998'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:44:37



**US3732304**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:26:54**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '0'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:44:37

**US3732304**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:26:54**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:44:37

**US3732304**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:26:54**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered empty.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:44:37

**US3732304**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:26:54**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '0'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:44:37

**US3732304**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered 'Jan 1998'	System	10 Sep 2020 17:44:37

**US3732304**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered '1998'	System	10 Sep 2020 17:44:37

**US3732304**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered empty.	System	10 Sep 2020 17:44:37

**US3732304**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered empty.	System	10 Sep 2020 17:44:37



US3732304

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:26:54

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Myopia, LLT: Myopia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 16:46:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 16:46:24
Data point term sent to Coder	System	19 Oct 2020 16:45:50
Coding entries removed.	Amara Yilmaz (b) (4) (b) (4)	19 Oct 2020 16:45:30
User entered 'MYOPIA bilateral' reason for change: New Information	Amara Yilmaz (b) (4) (b) (4)	19 Oct 2020 16:45:30
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Myopia, LLT: Myopia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 17:46:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 17:46:49
Data point term sent to Coder	System	10 Sep 2020 17:45:23
User entered 'myopia'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:44:47

**US3732304**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered 'un UNK 1974'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:44:47

**US3732304**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:26:54**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '0'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:44:47

**US3732304**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:26:54**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:44:47

**US3732304**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:26:54**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered empty.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:44:47

**US3732304**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:26:54**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '0'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:44:47

**US3732304**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered 'Jan 1974'	System	10 Sep 2020 17:44:47

**US3732304**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered '1974'	System	10 Sep 2020 17:44:47



**US3732304**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered empty.	System	10 Sep 2020 17:44:47

**US3732304**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered empty.	System	10 Sep 2020 17:44:47

US3732304

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:26:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Urinary tract infection, LLT: Urinary tract infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 17:47:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 17:47:38
Data point term sent to Coder	System	10 Sep 2020 17:46:27
User entered 'frequent urinary tract infections'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:45:28

**US3732304**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered 'un UNK 2015'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:45:28

**US3732304**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:26:54**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '0'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:45:28

**US3732304**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:26:54**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:45:28

**US3732304**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:26:54**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered empty.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:45:28

**US3732304**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:26:54**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '0'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:45:28



**US3732304**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered 'Jan 2015'	System	10 Sep 2020 17:45:28

**US3732304**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered '2015'	System	10 Sep 2020 17:45:28

**US3732304**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered empty.	System	10 Sep 2020 17:45:28

**US3732304**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered empty.	System	10 Sep 2020 17:45:28

US3732304

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:26:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Chronic back pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 16:53:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 16:53:49
Data point term sent to Coder	System	21 Sep 2020 16:52:55
User entered 'CHRONIC BACK PAIN' reason for change: New Information	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:52:21
Data point term sent to Coder	System	10 Sep 2020 17:46:27
User entered 'chronic neck and back pain'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:45:43

**US3732304**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered 'un UNK 2010'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:45:43

**US3732304**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:26:54**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '0'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:45:43

**US3732304**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:26:54**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:45:43



**US3732304**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:26:54**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered empty.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:45:43

**US3732304**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:26:54**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '0'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:45:43

**US3732304**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered 'Jan 2010'	System	10 Sep 2020 17:45:43

**US3732304**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered '2010'	System	10 Sep 2020 17:45:43

**US3732304**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered empty.	System	10 Sep 2020 17:45:43

**US3732304**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered empty.	System	10 Sep 2020 17:45:43

US3732304

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:26:54

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User coded data point as SOC: Psychiatric disorders, HLTG: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 17:47:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 17:47:37
Data point term sent to Coder	System	10 Sep 2020 17:46:28
User entered 'insomnia'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:45:53

**US3732304**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered 'un UNK 1996'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:45:53



**US3732304**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:26:54**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '0'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:45:53

**US3732304**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:26:54**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:45:53

**US3732304**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:26:54**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered empty.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:45:53

**US3732304**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:26:54**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '0'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:45:53

**US3732304**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered 'Jan 1996'	System	10 Sep 2020 17:45:53

**US3732304**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered '1996'	System	10 Sep 2020 17:45:53

**US3732304**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered empty.	System	10 Sep 2020 17:45:53

**US3732304**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered empty.	System	10 Sep 2020 17:45:53



US3732304

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:26:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 17:47:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 17:47:37
Data point term sent to Coder	System	10 Sep 2020 17:46:29
User entered 'depression'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:46:03

**US3732304**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered 'un UNK 1996'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:46:03

**US3732304**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:26:54**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '0'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:46:03

**US3732304**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:26:54**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:46:03

**US3732304**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:26:54**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered empty.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:46:03

**US3732304**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:26:54**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '0'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:46:03

**US3732304**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered 'Jan 1996'	System	10 Sep 2020 17:46:03

**US3732304**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered '1996'	System	10 Sep 2020 17:46:03



**US3732304**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered empty.	System	10 Sep 2020 17:46:03

**US3732304**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered empty.	System	10 Sep 2020 17:46:03

US3732304

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:26:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Menopause, LLT: Perimenopause - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 09:41:24
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 09:41:24
Data point term sent to Coder	System	10 Sep 2020 17:50:37
User entered 'peri menopause'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:50:37

**US3732304**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered 'un UNK 2017'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:50:37

**US3732304**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:26:54**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '0'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:50:37

**US3732304**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:26:54**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:50:37

**US3732304**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:26:54**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered empty.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:50:37

**US3732304**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:26:54**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '0'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:50:37



**US3732304**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered 'Jan 2017'	System	10 Sep 2020 17:50:37

**US3732304**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered '2017'	System	10 Sep 2020 17:50:37

**US3732304**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered empty.	System	10 Sep 2020 17:50:37

**US3732304**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered empty.	System	10 Sep 2020 17:50:37

US3732304

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:26:54

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User coded data point as SOC: Surgical and medical procedures, HLG: Renal and urinary tract therapeutic procedures, HLT: Bladder therapeutic procedures, PT: Cystocele repair, LLT: Cystocele repair - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 05:10:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 05:10:49
Data point term sent to Coder	System	10 Sep 2020 17:51:39
User entered 'cystocele surgery'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:51:24

**US3732304**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '16 Nov 2013'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:51:24

**US3732304**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:26:54**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '0'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:51:24

**US3732304**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:26:54**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:51:24



**US3732304**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:26:54**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '16 Nov 2013'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:51:24

**US3732304**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:26:54**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '0'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:51:24

**US3732304**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered 'Nov 2013'	System	10 Sep 2020 17:51:24

**US3732304**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered '2013'	System	10 Sep 2020 17:51:24

**US3732304**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered 'Nov 2013'	System	10 Sep 2020 17:51:24

**US3732304**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered '2013'	System	10 Sep 2020 17:51:24

US3732304

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:26:54

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User coded data point as SOC: Surgical and medical procedures, HLG: Renal and urinary tract therapeutic procedures, HLT: Bladder therapeutic procedures, PT: Cystocele repair, LLT: Cystocele repair - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 05:10:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 05:10:49
Data point term sent to Coder	System	10 Sep 2020 17:52:41
User entered 'cystocele surgery'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:51:49

**US3732304**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '17 Aug 2015'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:51:49



**US3732304**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:26:54**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '0'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:51:49

**US3732304**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:26:54**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:51:49

**US3732304**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:26:54**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '17 Aug 2015'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:51:49

**US3732304**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:26:54**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '0'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:51:49

**US3732304**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered 'Aug 2015'	System	10 Sep 2020 17:51:49

**US3732304**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered '2015'	System	10 Sep 2020 17:51:49

**US3732304**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered 'Aug 2015'	System	10 Sep 2020 17:51:49

**US3732304**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered '2015'	System	10 Sep 2020 17:51:49



US3732304

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:26:54

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User coded data point as SOC: Surgical and medical procedures, HLGT: Soft tissue therapeutic procedures, HLT: Tendon therapeutic procedures, PT: Tendon sheath incision, LLT: Trigger finger release - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 13:06:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 13:06:52
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:36:19
Data point term sent to Coder	System	03 Nov 2020 00:29:00
User closed query 'Per CDM Coding: Multiple medical concepts are reported. Please split into separate records, e.g. one of RIGHT TRIGGER FINGER RELEASE and one of CARPAL TUNNEL RELEASE etc.' (Site from System).	System	03 Nov 2020 00:28:18
Query 'Per CDM Coding: Multiple medical concepts are reported. Please split into separate records, e.g. one of RIGHT TRIGGER FINGER RELEASE and one of CARPAL TUNNEL RELEASE etc.' answered with 'updated' (Site from System).	Lauren Arnett (b) (4)	03 Nov 2020 00:28:18
User entered 'RIGHT TRIGGER FINGER RELEASE' reason for change: New Information	Lauren Arnett (b) (4)	03 Nov 2020 00:28:11
User opened query 'Per CDM Coding: Multiple medical concepts are reported. Please split into separate records, e.g. one of RIGHT TRIGGER FINGER RELEASE and one of CARPAL TUNNEL RELEASE etc.' (Site from System).	Coder Import (b) (4)	20 Oct 2020 12:22:29
Data point term sent to Coder	System	21 Sep 2020 16:52:56
Coding entries removed.	Lauren Arnett (b) (4)	21 Sep 2020 16:52:54
User entered 'RIGHT trigger finger - carpal tunnel release' reason for change: New Information	Lauren Arnett (b) (4)	21 Sep 2020 16:52:54
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Limb therapeutic procedures, PT: Limb operation, LLT: Hand operation - version MedDRA\23.0.	Coder Import (b) (4)	10 Sep 2020 17:53:47

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Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:26:54

[Condition](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	10 Sep 2020 17:53:47
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	10 Sep 2020 17:52:42
User entered 'right hand surgery'	Lauren Arnett (b) (4)	10 Sep 2020 17:52:06
	(b) (4)	

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**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '12 Jun 2020'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:52:06

**US3732304**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:26:54**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '0'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:52:06

**US3732304**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:26:54**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:52:06

**US3732304**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:26:54**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '12 Jun 2020'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:52:06

**US3732304**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:26:54**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '0'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:52:06

**US3732304**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered 'Jun 2020'	System	10 Sep 2020 17:52:06



**US3732304**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered '2020'	System	10 Sep 2020 17:52:06

**US3732304**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered 'Jun 2020'	System	10 Sep 2020 17:52:06

**US3732304**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered '2020'	System	10 Sep 2020 17:52:06

US3732304

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:26:54

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Neck pain, LLT: Neck pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 16:54:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 16:54:52
Data point term sent to Coder	System	21 Sep 2020 16:53:57
User entered 'chronic neck pain'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:53:13

**US3732304**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered 'un UNK 2010'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:53:13

**US3732304**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:26:54**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:53:13

**US3732304**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:26:54**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:53:13

**US3732304**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:26:54**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:53:13



**US3732304**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:26:54**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:53:13

**US3732304**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered 'Jan 2010'	System	21 Sep 2020 16:53:13

**US3732304**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered '2010'	System	21 Sep 2020 16:53:13

**US3732304**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered empty.	System	21 Sep 2020 16:53:13

**US3732304**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered empty.	System	21 Sep 2020 16:53:13

US3732304

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:26:54

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User coded data point as SOC: Reproductive system and breast disorders, HLG: Uterine, pelvic and broad ligament disorders, HLT: Pelvic prolapse conditions, PT: Cystocele, LLT: Cystocele - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 16:54:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 16:54:52
Data point term sent to Coder	System	21 Sep 2020 16:53:57
User entered 'cystocele'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:53:32

**US3732304**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '16 Nov 2013'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:53:32

**US3732304**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:26:54**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:53:32



**US3732304**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:26:54**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:53:32

**US3732304**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:26:54**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '16 Nov 2013'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:53:32

**US3732304**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:26:54**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:53:32

**US3732304**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered 'Nov 2013'	System	21 Sep 2020 16:53:32

**US3732304**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered '2013'	System	21 Sep 2020 16:53:32

**US3732304**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered 'Nov 2013'	System	21 Sep 2020 16:53:32

**US3732304**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered '2013'	System	21 Sep 2020 16:53:32

US3732304

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:26:54

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User coded data point as SOC: Reproductive system and breast disorders, HLG: Uterine, pelvic and broad ligament disorders, HLT: Pelvic prolapse conditions, PT: Cystocele, LLT: Cystocele - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 16:54:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 16:54:52
Data point term sent to Coder	System	21 Sep 2020 16:53:58
User entered 'cystocele'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:53:55



**US3732304**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '17 Aug 2015'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:53:55

**US3732304**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:26:54**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:53:55

**US3732304**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:26:54**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:53:55

**US3732304**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:26:54**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '17 Aug 2015'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:53:55

**US3732304**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:26:54**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:53:55

**US3732304**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered 'Aug 2015'	System	21 Sep 2020 16:53:55

**US3732304**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered '2015'	System	21 Sep 2020 16:53:55

**US3732304**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered 'Aug 2015'	System	21 Sep 2020 16:53:55



**US3732304**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered '2015'	System	21 Sep 2020 16:53:55

US3732304

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:26:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Peripheral nerve therapeutic procedures, PT: Carpal tunnel decompression, LLT: Carpal tunnel release - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Nov 2020 00:33:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Nov 2020 00:33:13
Data point term sent to Coder	System	03 Nov 2020 00:32:03
User closed query 'Per CDM Coding: Multiple medical concepts are reported. Please provide a unifying diagnosis, alternatively split into separate records, e.g. one of RIGHT TRIGGER FINGER and one of CARPAL TUNNEL SYNDROM etc.' (Site from System).	System	03 Nov 2020 00:31:22
Query 'Per CDM Coding: Multiple medical concepts are reported. Please provide a unifying diagnosis, alternatively split into separate records, e.g. one of RIGHT TRIGGER FINGER and one of CARPAL TUNNEL SYNDROM etc.' answered with 'updated' (Site from System).	Lauren Arnett (b) (4) (b) (4)	03 Nov 2020 00:31:22
User entered 'RIGHT carpal tunnel release' reason for change: New Information	Lauren Arnett (b) (4) (b) (4)	03 Nov 2020 00:31:11
User opened query 'Per CDM Coding: Multiple medical concepts are reported. Please provide a unifying diagnosis, alternatively split into separate records, e.g. one of RIGHT TRIGGER FINGER and one of CARPAL TUNNEL SYNDROM etc.' (Site from System).	Coder Import (b) (4) (b) (4)	20 Oct 2020 12:21:29
Data point term sent to Coder	System	21 Sep 2020 16:55:01
User entered 'right trigger finger- carpal tunnel'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:54:26

**US3732304**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '12 Jun 2020'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:54:26

**US3732304**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:26:54**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:54:26

**US3732304**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:26:54**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:54:26

**US3732304**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:26:54**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '12 Jun 2020'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:54:26

**US3732304**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:26:54**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:36:19
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:54:26

**US3732304**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered 'Jun 2020'	System	21 Sep 2020 16:54:26



**US3732304**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered '2020'	System	21 Sep 2020 16:54:26

**US3732304**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered 'Jun 2020'	System	21 Sep 2020 16:54:26

**US3732304**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered '2020'	System	21 Sep 2020 16:54:26

US3732304

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:26:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 21:12:20
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User closed query 'Per DM CLR: Please review medical diagnosis and confirm if this is a duplicate of medical condition MH# 17 (RIGHT CARPAL TUNNEL RELEASE). If yes, please ensure only one entry is recorded. Otherwise, provide comment. ' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 08:51:49
User coded data point as SOC: Nervous system disorders, HLT: Peripheral neuropathies, HLT: Mononeuropathies, PT: Carpal tunnel syndrome, LLT: Unilateral carpal tunnel syndrome - version MedDRA\23.0.	Coder Import (b) (4)	21 Jan 2021 23:02:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	21 Jan 2021 23:02:08
Query 'Per DM CLR: Please review medical diagnosis and confirm if this is a duplicate of medical condition MH# 17 (RIGHT CARPAL TUNNEL RELEASE). If yes, please ensure only one entry is recorded. Otherwise, provide comment. ' answered with 'data entry error, entry to be right carpal tunnel as to document the condition which led to the procedure ' (Site from DM).	Amara Yilmaz (b) (4)	21 Jan 2021 23:01:55
Data point term sent to Coder	System	21 Jan 2021 23:01:15
DataPoint Un-verified.	Amara Yilmaz (b) (4)	21 Jan 2021 23:01:11
Coding entries removed.	Amara Yilmaz (b) (4)	21 Jan 2021 23:01:11
User entered 'RIGHT CARPAL TUNNEL' reason for change: Data Entry Error	Amara Yilmaz (b) (4)	21 Jan 2021 23:01:11
User opened query 'Per DM CLR: Please review medical diagnosis and confirm if this is a duplicate of medical condition MH# 17 (RIGHT CARPAL TUNNEL RELEASE). If yes, please ensure only one entry is recorded. Otherwise, provide comment. ' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 02:21:39
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:04:19

US3732304

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:26:54

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Peripheral nerve therapeutic procedures, PT: Carpal tunnel decompression, LLT: Carpal tunnel release - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Nov 2020 00:13:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Nov 2020 00:13:25
Data point term sent to Coder	System	07 Nov 2020 00:12:16
User entered 'Right Carpal Tunnel Surgery'	(b) (4), (b) (6) (b) (4)	07 Nov 2020 00:11:28

US3732304

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:26:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 21:12:42
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Un-verified.	(b) (4) Gordon Bovee (b) (4)	16 Feb 2021 20:29:47
User entered 'un UNK 1994' reason for change: Data Entry Error	(b) (4) Gordon Bovee (b) (4)	16 Feb 2021 20:29:47
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:04:19
User entered '12 Jun 2020'	(b) (4), (b) (6)	07 Nov 2020 00:11:28

**US3732304**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:26:54**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:04:19
User entered '0'	(b) (4), (b) (6)	07 Nov 2020 00:11:28

**US3732304**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:26:54**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:04:19
User entered 'No (N)'	(b) (4), (b) (6)	07 Nov 2020 00:11:28



**US3732304**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:26:54**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:04:19
User entered '12 Jun 2020'	(b) (4), (b) (6)	07 Nov 2020 00:11:28

**US3732304**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:26:54**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 23:04:19
User entered '0'	(b) (4), (b) (6)	07 Nov 2020 00:11:28

**US3732304**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered 'Jan 1994'	System	16 Feb 2021 20:29:47
User entered 'Jun 2020'	System	07 Nov 2020 00:11:28

**US3732304**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered '1994'	System	16 Feb 2021 20:29:47
User entered '2020'	System	07 Nov 2020 00:11:28

**US3732304**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered 'Jun 2020'	System	07 Nov 2020 00:11:28

**US3732304**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered '2020'	System	07 Nov 2020 00:11:28

**US3732304**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:26:54**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:39:33
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:59:31

**US3732304**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:26:54**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:39:33
User entered '09 Sep 2020'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:59:31



**US3732304**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:26:54**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:39:33
User entered '14:48'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:59:31

**US3732304**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:26:54**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered '09 Sep 2020 14:48'	System	10 Sep 2020 17:59:31

**US3732304**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:26:54**

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:39:33
User entered '167.0' cm	Lauren Arnett (b) (4)	10 Sep 2020 17:59:31
DataPoint set to visible.	(b) (4) System	09 Sep 2020 23:12:58

**US3732304**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:26:54**

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:39:33
User entered '79.0' kg	Lauren Arnett (b) (4)	10 Sep 2020 17:59:31
DataPoint set to visible.	(b) (4) System	09 Sep 2020 23:12:58

**US3732304**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:26:54**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered '28.32658'	System	10 Sep 2020 17:59:31
DataPoint set to visible.	System	09 Sep 2020 23:12:58

**US3732304**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:26:54**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered 'kg/m2'	System	10 Sep 2020 17:59:31
DataPoint set to visible.	System	09 Sep 2020 23:12:58

**US3732304**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:26:54**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:39:33
User entered missing code ND - Not Done.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:59:31

**US3732304**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:26:54**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:39:33
User entered empty.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:59:31



**US3732304**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:26:54**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:39:33
User entered empty.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:59:31

**US3732304**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:26:54**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:39:33
User entered missing code ND - Not Done.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:59:31

US3732304

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
Query 'Per CDM: Units of measure ( Pulse BPM, Respiratory Rate BREATHS/MIN, Systolic and Diastolic Blood Pressure MMHG ) should not be recorded if value is blank or ND. Thank you. ' canceled (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 20:59:32
User opened query 'Per CDM: Units of measure ( Pulse BPM, Respiratory Rate BREATHS/MIN, Systolic and Diastolic Blood Pressure MMHG ) should not be recorded if value is blank or ND. Thank you. ' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 07:47:46
User entered 'bpm'	System	10 Sep 2020 17:59:31

**US3732304**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:26:54**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:39:33
User entered missing code ND - Not Done.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:59:31

**US3732304**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:26:54**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered 'breaths/min'	System	10 Sep 2020 17:59:31

**US3732304**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:26:54**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:39:33
User entered missing code ND - Not Done.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:59:31

**US3732304**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:26:54**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered 'mmHg'	System	10 Sep 2020 17:59:31

**US3732304**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:26:54**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:39:33
User entered missing code ND - Not Done.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:59:31



**US3732304**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:26:54**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered 'mmHg'	System	10 Sep 2020 17:59:31

**US3732304**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:26:54**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59

**US3732304**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:26:54**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59

**US3732304**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:26:54**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:40:17
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:59:39

**US3732304**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:26:54**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:40:17
User entered '09 Sep 2020'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 17:59:39

US3732304

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:26:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:40:33
User entered '09 Sep 2020'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:01:20

**US3732304**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:26:54**

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:40:33
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:01:20

**US3732304**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:26:54**

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:40:33
User entered empty.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:01:20



**US3732304**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:26:54**

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:40:33
User entered empty.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:01:20

**US3732304**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:40:33
User entered empty.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:01:20

**US3732304**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:26:54**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:40:33
User entered '0'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:01:20

**US3732304**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:26:54**

*If Post-menopausal, date of last menstruation (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:40:33
User entered empty.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:01:20

**US3732304**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:26:54**

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:40:33
User entered '0'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:01:20

**US3732304**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:26:54**

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:40:44
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:01:35

**US3732304**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:26:54**

**Date of test (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:40:44
User entered '09 Sep 2020'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:01:35

**US3732304**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:26:54**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:40:44
User entered 'Urine (URINE)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:01:35



**US3732304**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:26:54**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:40:44
User entered 'Negative (NEGATIVE)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:01:35

**US3732304**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:26:54**

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:40:44
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:01:35

**US3732304**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:26:54**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:40:44
User entered empty.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:01:35

**US3732304**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:26:54**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:40:44
User entered empty.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:01:35

**US3732304**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:26:54**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered empty.	System	10 Sep 2020 18:01:35

US3732304

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:26:54

[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 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:41:27
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:02:26

**US3732304**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:26:54**

**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 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:41:27
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:02:26

US3732304

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:26:54

**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 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:41:27
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:02:26



US3732304

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:26:54

**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 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:41:27
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:02:26

US3732304

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:26:54

[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 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:41:27
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:02:26

US3732304

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:26:54

[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 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:41:27
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:02:26

US3732304

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:26:54

**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 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:41:27
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:02:26

US3732304

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:26:54

**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 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:41:27
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:02:26

US3732304

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:26:54

[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 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:41:27
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:02:26

US3732304

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:26:54

**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 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:41:27
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:02:26

US3732304

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:26:54

**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 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:41:27
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:02:26



**US3732304**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:26:54**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:41:27
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:02:26

**US3732304**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:26:54**

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:41:27
User entered empty.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:02:26

**US3732304**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:26:54**

**No Risk Identified**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
User entered '0'	Lauren Arnett (b) (4)	10 Sep 2020 18:02:26

US3732304

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:26:54

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:41:27
User entered '0'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:02:26

US3732304

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:26:54

**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 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:41:27
User entered '0'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:02:26

US3732304

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:26:54

[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 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:41:27
User entered 'l'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:02:26

US3732304

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:26:54

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 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:41:27
User entered '0'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:02:26

**US3732304**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:26:54**

**Resides in a single family home** (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:41:27
User entered '0'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:02:26



**US3732304**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:26:54**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
User entered '0'	Lauren Arnett (b) (4)	10 Sep 2020 18:02:26

**US3732304**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:26:54**

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:41:27
User entered empty.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:02:26

**US3732304**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:26:54**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:16
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:42:36
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	10 Sep 2020 18:02:44

**US3732304**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:16
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:42:36
User entered '09 Sep 2020'	Lauren Arnett (b) (4)	10 Sep 2020 18:02:44

**US3732304**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:16
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:42:36
User entered 'Clinic (Clinic)'	Lauren Arnett (b) (4)	10 Sep 2020 18:02:44

**US3732304**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:26:54**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:16
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User entered 'VISIT1'	System	10 Sep 2020 18:02:44

US3732304

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:26:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:21
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:43:14
User entered '09 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 22:24:20

US3732304

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:26:54

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:21
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:43:14
User entered '112827'	RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 22:24:20



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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:26:54

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:21
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:43:14
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 22:24:20

US3732304

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:26:54

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)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:21
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:43:14
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:03:15

US3732304

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:26:54

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)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:21
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:43:14
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:03:15

**US3732304**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:26:54**

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:21
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:43:14
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:03:15

**US3732304**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:26:54**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:21
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:43:14
User entered 'No (N)'	Lauren Arnett (b) (4)	10 Sep 2020 18:03:15

US3732304

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:26:54

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:21
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:43:14
User entered 'No (N)'	Lauren Arnett (b) (4)	10 Sep 2020 18:03:15

US3732304

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:26:54

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:21
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:43:14
User entered 'No (N)'	Lauren Arnett (b) (4)	21 Sep 2020 16:52:01
Amendment Manager: DataPoint set to visible.	(b) (4)	
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:54:08
	System	19 Sep 2020 05:54:06

US3732304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:26:54

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:28
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:02:56
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) (6)	21 Sep 2020 17:41:56
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)	21 Sep 2020 16:51:55
User entered missing code ND - Not Done; reason for change Data Entry Error	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:51:46
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 14:35:46



US3732304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:26:54

Height

Audit	User	Time (GMT)
User entered empty.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:05:04

US3732304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:26:54

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:28
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:02:56
User entered missing code ND - Not Done; reason for change Data Entry Error	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:51:46
User entered empty.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:05:04

US3732304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:26:54

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:28
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:02:56
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) (6)	21 Sep 2020 17:41:56
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)	21 Sep 2020 16:51:55
User entered missing code ND - Not Done; reason for change Data Entry Error	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:51:46
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 14:35:46

US3732304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:26:54

Height

Audit	User	Time (GMT)
User entered empty.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:05:04

US3732304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:26:54

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:28
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:02:56
User entered missing code ND - Not Done; reason for change Data Entry Error	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:51:46
User entered empty.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:05:04

US3732304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:28
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User accepted default value 'Pre-Dose (PREDOSE)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:05:04

US3732304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:28
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:02:56
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	10 Sep 2020 18:05:04

**US3732304**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:28
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:02:56
User entered '09 Sep 2020'	Lauren Arnett (b) (4)	10 Sep 2020 18:05:04



**US3732304**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:28
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:02:56
User entered '14:48'	Lauren Arnett (b) (4)	10 Sep 2020 18:05:04

**US3732304**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:28
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User entered '09 Sep 2020 14:48'	System	10 Sep 2020 18:05:04

US3732304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:28
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:02:56
User entered '98.7' F	Lauren Arnett (b) (4)	10 Sep 2020 18:05:04

US3732304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:28
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:02:56
User entered 'Oral (Oral)'	Lauren Arnett (b) (4)	10 Sep 2020 18:05:04

US3732304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:28
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:02:56
User entered empty.	Lauren Arnett (b) (4)	10 Sep 2020 18:05:04

US3732304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:28
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:02:56
User entered '90'	Lauren Arnett (b) (4)	10 Sep 2020 18:05:04

**US3732304**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:28
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User entered 'bpm'	System	10 Sep 2020 18:05:04

US3732304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:54

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:28
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:02:56
User entered '16'	Lauren Arnett (b) (4)	10 Sep 2020 18:05:04



US3732304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:28
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User entered 'breaths/min'	System	10 Sep 2020 18:05:04

US3732304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:28
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:02:56
User entered '126'	Lauren Arnett (b) (4)	10 Sep 2020 18:05:04

US3732304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:28
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User entered 'mmHg'	System	10 Sep 2020 18:05:04

US3732304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:28
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:02:56
User entered '86'	Lauren Arnett (b) (4)	10 Sep 2020 18:05:04

**US3732304**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:28
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User entered 'mmHg'	System	10 Sep 2020 18:05:04

US3732304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:26:54

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:28
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:02:56
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) (6)	21 Sep 2020 17:41:56
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)	21 Sep 2020 16:51:55
User entered missing code ND - Not Done; reason for change Data Entry Error	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:51:46
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 14:35:46

US3732304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:26:54

Height

Audit	User	Time (GMT)
User entered empty.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:05:04

US3732304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:26:54

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:28
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:02:56
User entered missing code ND - Not Done; reason for change Data Entry Error	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:51:46
User entered empty.	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:05:04



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:28
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User accepted default value 'Post-Dose (POSTDOSE)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:05:04

US3732304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:28
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:02:56
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	10 Sep 2020 18:05:04

US3732304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:28
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:02:56
User entered '09 Sep 2020'	Lauren Arnett (b) (4)	10 Sep 2020 18:05:04

**US3732304**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:26:54**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:28
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:02:56
User entered '16:37'	Lauren Arnett (b) (4)	10 Sep 2020 18:05:04

**US3732304**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:28
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User entered '09 Sep 2020 16:37'	System	10 Sep 2020 18:05:04

US3732304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:28
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:02:56
User entered '98.4' F	Lauren Arnett (b) (4)	10 Sep 2020 18:05:04

US3732304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:28
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:02:56
User entered 'Oral (Oral)'	Lauren Arnett (b) (4)	10 Sep 2020 18:05:04

US3732304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:28
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:02:56
User entered empty.	Lauren Arnett (b) (4)	10 Sep 2020 18:05:04



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:28
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:02:56
User entered '89'	Lauren Arnett (b) (4)	10 Sep 2020 18:05:04

**US3732304**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:28
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User entered 'bpm'	System	10 Sep 2020 18:05:04

US3732304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:54

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:28
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:02:56
User entered '16'	Lauren Arnett (b) (4)	10 Sep 2020 18:05:04

US3732304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:28
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User entered 'breaths/min'	System	10 Sep 2020 18:05:04

US3732304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:28
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:02:56
User entered '113'	Lauren Arnett (b) (4)	10 Sep 2020 18:05:04

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:28
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User entered 'mmHg'	System	10 Sep 2020 18:05:04

US3732304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:28
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:02:56
User entered '77'	Lauren Arnett (b) (4)	10 Sep 2020 18:05:04

**US3732304**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:28
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User entered 'mmHg'	System	10 Sep 2020 18:05:04



US3732304

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:26:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:35
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:01
User entered 'No (N)'	Lauren Arnett (b) (4)	10 Sep 2020 18:05:09

US3732304

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:26:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:35
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:01
User entered empty.	Lauren Arnett (b) (4)	10 Sep 2020 18:05:09

**US3732304**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:26:54**

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:38
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:26
User entered 'No (N)'	Lauren Arnett (b) (4)	10 Sep 2020 18:05:14

US3732304

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:26:54

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:38
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:27
User entered empty.	Lauren Arnett (b) (4)	10 Sep 2020 18:05:14

**US3732304**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:26:54**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:38
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:29
User entered empty.	Lauren Arnett (b) (4)	10 Sep 2020 18:05:14

**US3732304**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:26:54**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:38
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:30
User entered empty.	Lauren Arnett (b) (4)	10 Sep 2020 18:05:14

US3732304

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:26:54

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:38
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
User closed query 'per CDM: please select yes or no for this field' (Site from DM).	(b) (4)	12 Nov 2020 20:59:12
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 23:05:14
Query 'per CDM: please select yes or no for this field' answered with 'updated ' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 00:25:33
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Nov 2020 00:25:29
User opened query 'per CDM: please select yes or no for this field' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 15:34:23
User entered empty.	Lauren Arnett (b) (4)	10 Sep 2020 18:05:14
	(b) (4)	

**US3732304**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:26:54**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:38
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:32
User entered empty.	Lauren Arnett (b) (4)	10 Sep 2020 18:05:14



**US3732304**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:26:54**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:38
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:05:34
User entered empty.	Lauren Arnett (b) (4)	10 Sep 2020 18:05:14

**US3732304**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:26:54**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:38
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User entered empty.	System	10 Sep 2020 18:05:14

US3732304

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:26:54

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:43
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:06:28
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	09 Sep 2020 23:13:18

US3732304

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:26:54

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:43
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:06:28
User entered empty.	Lauren Arnett (b) (4)	09 Sep 2020 23:13:18

US3732304

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:26:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:43
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:06:28
User entered empty.	Lauren Arnett (b) (4) (b) (4)	09 Sep 2020 23:13:18

**US3732304**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:26:54**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:43
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User entered 'MRNA-1273 OR PLACEBO'	System	09 Sep 2020 23:13:18

US3732304

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:26:54

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:43
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:06:28
User entered '09 Sep 2020'	Lauren Arnett (b) (4)	09 Sep 2020 23:13:18

**US3732304**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:26:54**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:43
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:06:28
User entered '16:07'	Lauren Arnett (b) (4)	09 Sep 2020 23:13:18



**US3732304**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:26:54**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:43
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User entered '09 Sep 2020 16:07'	System	09 Sep 2020 23:13:18

US3732304

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:26:54

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:43
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:06:28
User entered 'Right Arm (RIGHT ARM)'	Lauren Arnett (b) (4) (b) (4)	09 Sep 2020 23:13:18

US3732304

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:26:54

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:43
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:06:28
User entered 'ONCE'	System	09 Sep 2020 23:13:18

**US3732304**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:26:54**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:43
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User entered 'INTRAMUSCULAR'	System	09 Sep 2020 23:13:18

US3732304

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:26:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:46
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:06:52
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	10 Sep 2020 18:05:31

US3732304

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:26:54

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:46
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:06:52
User entered '09 Sep 2020'	Lauren Arnett (b) (4)	10 Sep 2020 18:05:31

**US3732304**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:26:54**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:46
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:06:52
User entered '15:27'	Lauren Arnett (b) (4)	10 Sep 2020 18:05:31

**US3732304**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:26:54**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:46
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User entered '09 Sep 2020 15:27'	System	10 Sep 2020 18:05:31



US3732304

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:26:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:50
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:07:01
User entered '09 Sep 2020'	Lauren Arnett (b) (4)	10 Sep 2020 18:05:41

US3732304

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:26:54

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:50
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:05:41

US3732304

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:26:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:50
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:07:01
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	10 Sep 2020 18:05:41

**US3732304**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:50
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:07:01
User entered '15:23'	Lauren Arnett (b) (4)	10 Sep 2020 18:05:41

**US3732304**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:50
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User entered '09 Sep 2020 15:23'	System	10 Sep 2020 18:05:41

US3732304

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:26:54

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:50
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Lauren Arnett (b) (4) (b) (4)	10 Sep 2020 18:05:41

US3732304

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:26:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:50
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:07:01
User entered 'No (N)'	Lauren Arnett (b) (4)	10 Sep 2020 18:05:41

**US3732304**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:50
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:07:01
User entered empty.	Lauren Arnett (b) (4)	10 Sep 2020 18:05:41



**US3732304**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:50
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User entered empty.	System	10 Sep 2020 18:05:41

US3732304

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:26:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:53
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:07:08
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	10 Sep 2020 18:05:48

**US3732304**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:26:54**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:23:53
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User entered 'I'	System	10 Sep 2020 18:05:48

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
Data entry locked.	System	09 Sep 2020 23:13:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:26:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-09T16:43:02', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'd7b2d65d-3d50-4387-98b5-98940cbf3990'	System	09 Sep 2020 23:43:25
User entered 'Yes (Y)'	System	09 Sep 2020 23:43:25

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:26:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-09T16:43:09', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'd7b2d65d-3d50-4387-98b5-98940cbf3990'	System	09 Sep 2020 23:43:25
User entered '98.4'	System	09 Sep 2020 23:43:25

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:26:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-09T16:43:14', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'd7b2d65d-3d50-4387-98b5-98940cbf3990'	System	09 Sep 2020 23:43:25
User entered 'No (N)'	System	09 Sep 2020 23:43:25

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-09T16:43:21', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'd7b2d65d-3d50-4387-98b5-98940cbf3990'	System	09 Sep 2020 23:43:25
User entered '09 Sep 2020 16:43'	System	09 Sep 2020 23:43:25



**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '09 Sep 2020 16:27'	System	09 Sep 2020 23:13:18

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '09 Sep 2020 18:57'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:26:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
Data entry locked.	System	09 Sep 2020 23:13:18
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:26:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:26:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:26:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:26:54

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:26:54

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03



**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '09 Sep 2020 19:52'	System	09 Sep 2020 23:13:18

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 23:13:18

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
Data entry locked.	System	09 Sep 2020 23:13:18
User entered 'Day 2'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:26:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-10T19:03:20', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'd85ddf7c-6e80-4ab8-aae1-ef665d2db0fd'	System	11 Sep 2020 02:04:44
User entered 'Yes (Y)'	System	11 Sep 2020 02:04:44

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:26:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-10T19:04:28', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'd85ddf7c-6e80-4ab8-aae1-ef665d2db0fd'	System	11 Sep 2020 02:04:44
User entered '99.0'	System	11 Sep 2020 02:04:44

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:26:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-10T19:04:31', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'd85ddf7c-6e80-4ab8-aae1-ef665d2db0fd'	System	11 Sep 2020 02:04:44
User entered 'No (N)'	System	11 Sep 2020 02:04:44

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-10T19:04:38', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'd85ddf7c-6e80-4ab8-aae1-ef665d2db0fd'	System	11 Sep 2020 02:04:44
User entered '10 Sep 2020 19:04'	System	11 Sep 2020 02:04:44



**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 23:13:18

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:26:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
Data entry locked.	System	09 Sep 2020 23:13:18
User entered 'Day 3'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:26:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-11T21:59:32', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '994300a2-4884-490e-81fb-5a6087d41740'	System	12 Sep 2020 05:00:43
User entered 'Yes (Y)'	System	12 Sep 2020 05:00:43

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:26:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-11T22:00:23', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '994300a2-4884-490e-81fb-5a6087d41740'	System	12 Sep 2020 05:00:43
User entered '98.9'	System	12 Sep 2020 05:00:43

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:26:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-11T22:00:34', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '994300a2-4884-490e-81fb-5a6087d41740'	System	12 Sep 2020 05:00:43
User entered 'No (N)'	System	12 Sep 2020 05:00:43

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:26:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-11T22:00:38', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '994300a2-4884-490e-81fb-5a6087d41740'	System	12 Sep 2020 05:00:43
User entered '11 Sep 2020 22:00'	System	12 Sep 2020 05:00:43

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 23:13:18



**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:26:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
Data entry locked.	System	09 Sep 2020 23:13:18
User entered 'Day 4'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:26:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-12T22:30:04', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '49e2c631-ff18-4391-9fca-1695204b7001'	System	13 Sep 2020 05:30:32
User entered 'Yes (Y)'	System	13 Sep 2020 05:30:32

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:26:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-12T22:30:12', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '49e2c631-ff18-4391-9fca-1695204b7001'	System	13 Sep 2020 05:30:32
User entered '98.1'	System	13 Sep 2020 05:30:32

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:26:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-12T22:30:17', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '49e2c631-ff18-4391-9fca-1695204b7001'	System	13 Sep 2020 05:30:32
User entered 'Yes (Y)'	System	13 Sep 2020 05:30:32

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:26:54

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'medication taken for past medical history' (Site from System).	(b) (4), (b) (6)	18 Sep 2020 12:33:25
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Lauren Arnett (b) (4)	17 Sep 2020 17:56:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-12T22:30:24', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '49e2c631-ff18-4391-9fca-1695204b7001'	System	13 Sep 2020 05:30:32
User entered '1'	System	13 Sep 2020 05:30:32

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:26:54

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-12T22:30:24', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '49e2c631-ff18-4391-9fca-1695204b7001'	System	13 Sep 2020 05:30:32
User entered '0'	System	13 Sep 2020 05:30:32

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-12T22:30:29', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '49e2c631-ff18-4391-9fca-1695204b7001'	System	13 Sep 2020 05:30:32
User entered '12 Sep 2020 22:30'	System	13 Sep 2020 05:30:32



**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 23:13:18

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:26:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
Data entry locked.	System	09 Sep 2020 23:13:18
User entered 'Day 5'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:26:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-13T21:45:34', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '7fc52a77-2952-4eeb-b1d4-d77f6195c6fe'	System	14 Sep 2020 04:45:50
User entered 'Yes (Y)'	System	14 Sep 2020 04:45:50

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:26:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-13T21:45:38', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '7fc52a77-2952-4eeb-b1d4-d77f6195c6fe'	System	14 Sep 2020 04:45:50
User entered '98.4'	System	14 Sep 2020 04:45:50

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:26:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-13T21:45:42', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '7fc52a77-2952-4eeb-b1d4-d77f6195c6fe'	System	14 Sep 2020 04:45:50
User entered 'No (N)'	System	14 Sep 2020 04:45:50

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-13T21:45:46', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '7fc52a77-2952-4eeb-b1d4-d77f6195c6fe'	System	14 Sep 2020 04:45:50
User entered '13 Sep 2020 21:45'	System	14 Sep 2020 04:45:50

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 23:13:18



**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:26:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
Data entry locked.	System	09 Sep 2020 23:13:18
User entered 'Day 6'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:26:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-14T18:03:31', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'f95a9803-da1e-4db2-acac-41fe9b1fd603'	System	15 Sep 2020 01:03:44
User entered 'Yes (Y)'	System	15 Sep 2020 01:03:44

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:26:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-14T18:03:36', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'f95a9803-da1e-4db2-acac-41fe9b1fd603'	System	15 Sep 2020 01:03:44
User entered '98.9'	System	15 Sep 2020 01:03:44

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:26:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-14T18:03:39', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'f95a9803-da1e-4db2-acac-41fe9b1fd603'	System	15 Sep 2020 01:03:44
User entered 'No (N)'	System	15 Sep 2020 01:03:44

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-14T18:03:41', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'f95a9803-da1e-4db2-acac-41fe9b1fd603'	System	15 Sep 2020 01:03:44
User entered '14 Sep 2020 18:03'	System	15 Sep 2020 01:03:44

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 23:13:18

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 23:13:18



US3732304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:26:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
Data entry locked.	System	09 Sep 2020 23:13:18
User entered 'Day 7'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:26:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-15T19:05:16', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'b3a1fb8c-d908-4055-8396-3ee4711e1ab5'	System	16 Sep 2020 02:05:31
User entered 'Yes (Y)'	System	16 Sep 2020 02:05:31

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:26:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-15T19:05:19', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'b3a1fb8c-d908-4055-8396-3ee4711e1ab5'	System	16 Sep 2020 02:05:31
User entered '99.1'	System	16 Sep 2020 02:05:31

US3732304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:26:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-15T19:05:22', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'b3a1fb8c-d908-4055-8396-3ee4711e1ab5'	System	16 Sep 2020 02:05:31
User entered 'No (N)'	System	16 Sep 2020 02:05:31

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-15T19:05:26', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'b3a1fb8c-d908-4055-8396-3ee4711e1ab5'	System	16 Sep 2020 02:05:31
User entered '15 Sep 2020 19:05'	System	16 Sep 2020 02:05:31

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 23:13:18

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:26:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
Data entry locked.	System	09 Sep 2020 23:13:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 23:13:18



US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:26:54

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 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-09T16:43:32', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '37ab9602-5633-41c8-9fda-1900e0d4eaf7'	System	09 Sep 2020 23:43:52
User entered 'None (1)'	System	09 Sep 2020 23:43:52

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:26:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-09T16:43:35', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '37ab9602-5633-41c8-9fda-1900e0d4eaf7'	System	09 Sep 2020 23:43:52
User entered 'No (N)'	System	09 Sep 2020 23:43:52

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:26:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-09T16:43:38', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '37ab9602-5633-41c8-9fda-1900e0d4eaf7'	System	09 Sep 2020 23:43:52
User entered 'No (N)'	System	09 Sep 2020 23:43:52

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:26:54

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 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-09T16:43:41', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '37ab9602-5633-41c8-9fda-1900e0d4eaf7'	System	09 Sep 2020 23:43:52
User entered 'None (1)'	System	09 Sep 2020 23:43:52

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-09T16:43:46', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '37ab9602-5633-41c8-9fda-1900e0d4eaf7'	System	09 Sep 2020 23:43:52
User entered '09 Sep 2020 16:43'	System	09 Sep 2020 23:43:52

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '09 Sep 2020 16:27'	System	09 Sep 2020 23:13:18

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '09 Sep 2020 18:57'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:26:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
Data entry locked.	System	09 Sep 2020 23:13:18
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 23:13:18



US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:26:54

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 16:22:03

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:26:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:26:54

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:26:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:26:54

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:26:54

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 16:22:03

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '09 Sep 2020 19:52'	System	09 Sep 2020 23:13:18



**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:26:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
Data entry locked.	System	09 Sep 2020 23:13:18
User entered 'Day 2'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:26:54

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 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-10T19:04:45', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '1fe9cda7-3049-426e-b359-d1910b81c3fe'	System	11 Sep 2020 02:05:06
User entered 'None (1)'	System	11 Sep 2020 02:05:06

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:26:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-10T19:04:48', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '1fe9cda7-3049-426e-b359-d1910b81c3fe'	System	11 Sep 2020 02:05:06
User entered 'No (N)'	System	11 Sep 2020 02:05:06

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:26:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-10T19:04:53', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '1fe9cda7-3049-426e-b359-d1910b81c3fe'	System	11 Sep 2020 02:05:06
User entered 'No (N)'	System	11 Sep 2020 02:05:06

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:26:54

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 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-10T19:04:58', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '1fe9cda7-3049-426e-b359-d1910b81c3fe'	System	11 Sep 2020 02:05:06
User entered 'None (1)'	System	11 Sep 2020 02:05:06

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-10T19:05:02', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '1fe9cda7-3049-426e-b359-d1910b81c3fe'	System	11 Sep 2020 02:05:06
User entered '10 Sep 2020 19:05'	System	11 Sep 2020 02:05:06

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 23:13:18



**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 23:13:18

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
Data entry locked.	System	09 Sep 2020 23:13:18
User entered 'Day 3'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:26:54

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 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-11T21:43:41', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'fc168b2f-b377-4b1a-a725-a6555cc682dd'	System	12 Sep 2020 04:44:04
User entered 'None (1)'	System	12 Sep 2020 04:44:04

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:26:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-11T21:43:46', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'fc168b2f-b377-4b1a-a725-a6555cc682dd'	System	12 Sep 2020 04:44:04
User entered 'No (N)'	System	12 Sep 2020 04:44:04

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:26:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-11T21:43:48', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'fc168b2f-b377-4b1a-a725-a6555cc682dd'	System	12 Sep 2020 04:44:04
User entered 'No (N)'	System	12 Sep 2020 04:44:04

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:26:54

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 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-11T21:43:51', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'fc168b2f-b377-4b1a-a725-a6555cc682dd'	System	12 Sep 2020 04:44:04
User entered 'None (1)'	System	12 Sep 2020 04:44:04

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-11T21:43:58', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'fc168b2f-b377-4b1a-a725-a6555cc682dd'	System	12 Sep 2020 04:44:04
User entered '11 Sep 2020 21:43'	System	12 Sep 2020 04:44:04

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 23:13:18



**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 23:13:18

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
Data entry locked.	System	09 Sep 2020 23:13:18
User entered 'Day 4'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:26:54

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 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-12T22:30:53', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'f50a3003-fc61-4de0-a86a-2586583707a6'	System	13 Sep 2020 05:30:59
User entered 'None (1)'	System	13 Sep 2020 05:30:59

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:26:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-12T22:30:51', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'f50a3003-fc61-4de0-a86a-2586583707a6'	System	13 Sep 2020 05:30:59
User entered 'No (N)'	System	13 Sep 2020 05:30:59

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:26:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-12T22:30:49', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'f50a3003-fc61-4de0-a86a-2586583707a6'	System	13 Sep 2020 05:30:59
User entered 'No (N)'	System	13 Sep 2020 05:30:59

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:26:54

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 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-12T22:30:49', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'f50a3003-fc61-4de0-a86a-2586583707a6'	System	13 Sep 2020 05:30:59
User entered 'None (1)'	System	13 Sep 2020 05:30:59

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:26:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-12T22:30:56', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'f50a3003-fc61-4de0-a86a-2586583707a6'	System	13 Sep 2020 05:30:59
User entered '12 Sep 2020 22:30'	System	13 Sep 2020 05:30:59

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 23:13:18



**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 23:13:18

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
Data entry locked.	System	09 Sep 2020 23:13:18
User entered 'Day 5'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:26:54

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 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-13T21:45:51', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '95aa360d-52f4-4126-964f-3a77a71fd7f4'	System	14 Sep 2020 04:46:07
User entered 'None (1)'	System	14 Sep 2020 04:46:07

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:26:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-13T21:45:54', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '95aa360d-52f4-4126-964f-3a77a71fd7f4'	System	14 Sep 2020 04:46:07
User entered 'No (N)'	System	14 Sep 2020 04:46:07

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:26:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-13T21:45:56', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '95aa360d-52f4-4126-964f-3a77a71fd7f4'	System	14 Sep 2020 04:46:07
User entered 'No (N)'	System	14 Sep 2020 04:46:07

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:26:54

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 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-13T21:45:59', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '95aa360d-52f4-4126-964f-3a77a71fd7f4'	System	14 Sep 2020 04:46:07
User entered 'None (1)'	System	14 Sep 2020 04:46:07

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:26:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-13T21:46:02', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '95aa360d-52f4-4126-964f-3a77a71fd7f4'	System	14 Sep 2020 04:46:07
User entered '13 Sep 2020 21:46'	System	14 Sep 2020 04:46:07

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 23:13:18



**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 23:13:18

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
Data entry locked.	System	09 Sep 2020 23:13:18
User entered 'Day 6'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:26:54

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 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-14T18:02:27', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '98ae7581-1ae7-4754-a0b1-c678b12a3426'	System	15 Sep 2020 01:02:45
User entered 'None (1)'	System	15 Sep 2020 01:02:45

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:26:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-14T18:02:32', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '98ae7581-1ae7-4754-a0b1-c678b12a3426'	System	15 Sep 2020 01:02:45
User entered 'No (N)'	System	15 Sep 2020 01:02:45

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:26:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-14T18:02:35', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '98ae7581-1ae7-4754-a0b1-c678b12a3426'	System	15 Sep 2020 01:02:45
User entered 'No (N)'	System	15 Sep 2020 01:02:45

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:26:54

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 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-14T18:02:38', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '98ae7581-1ae7-4754-a0b1-c678b12a3426'	System	15 Sep 2020 01:02:45
User entered 'None (1)'	System	15 Sep 2020 01:02:45

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-14T18:02:42', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '98ae7581-1ae7-4754-a0b1-c678b12a3426'	System	15 Sep 2020 01:02:45
User entered '14 Sep 2020 18:02'	System	15 Sep 2020 01:02:45

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 23:13:18



**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 23:13:18

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
Data entry locked.	System	09 Sep 2020 23:13:18
User entered 'Day 7'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:26:54

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 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-15T19:05:30', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '5a9a87e6-5206-4495-9226-b9c6d82af47c'	System	16 Sep 2020 02:05:46
User entered 'None (1)'	System	16 Sep 2020 02:05:46

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:26:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-15T19:05:33', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '5a9a87e6-5206-4495-9226-b9c6d82af47c'	System	16 Sep 2020 02:05:46
User entered 'No (N)'	System	16 Sep 2020 02:05:46

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:26:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-15T19:05:36', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '5a9a87e6-5206-4495-9226-b9c6d82af47c'	System	16 Sep 2020 02:05:46
User entered 'No (N)'	System	16 Sep 2020 02:05:46

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:26:54

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 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-15T19:05:39', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '5a9a87e6-5206-4495-9226-b9c6d82af47c'	System	16 Sep 2020 02:05:46
User entered 'None (1)'	System	16 Sep 2020 02:05:46

US3732304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:26:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-15T19:05:41', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '5a9a87e6-5206-4495-9226-b9c6d82af47c'	System	16 Sep 2020 02:05:46
User entered '15 Sep 2020 19:05'	System	16 Sep 2020 02:05:46

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 23:13:18



**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 23:13:18

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
Data entry locked.	System	09 Sep 2020 23:13:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:26:54

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-09T16:43:52', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '55b1ccbc-e788-4013-bfac-04ac20e63c21'	System	09 Sep 2020 23:44:17
User entered 'None (0)'	System	09 Sep 2020 23:44:17

US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:26:54

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-09T16:43:55', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '55b1ccbc-e788-4013-bfac-04ac20e63c21'	System	09 Sep 2020 23:44:17
User entered 'None (0)'	System	09 Sep 2020 23:44:17

US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:26:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-09T16:43:57', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '55b1ccbc-e788-4013-bfac-04ac20e63c21'	System	09 Sep 2020 23:44:17
User entered 'None (0)'	System	09 Sep 2020 23:44:17

US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:26:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-09T16:44:00', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '55b1ccbc-e788-4013-bfac-04ac20e63c21'	System	09 Sep 2020 23:44:17
User entered 'None (0)'	System	09 Sep 2020 23:44:17

US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:26:54

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-09T16:44:02', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '55b1ccbc-e788-4013-bfac-04ac20e63c21'	System	09 Sep 2020 23:44:17
User entered 'None (0)'	System	09 Sep 2020 23:44:17

US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:26:54

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-09T16:44:04', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '55b1ccbc-e788-4013-bfac-04ac20e63c21'	System	09 Sep 2020 23:44:17
User entered 'None (0)'	System	09 Sep 2020 23:44:17



US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:26:54

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 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-09T16:44:09', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '55b1ccbc-e788-4013-bfac-04ac20e63c21'	System	09 Sep 2020 23:44:17
User entered 'No (N)'	System	09 Sep 2020 23:44:17

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-09T16:44:12', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '55b1ccbc-e788-4013-bfac-04ac20e63c21'	System	09 Sep 2020 23:44:17
User entered '09 Sep 2020 16:44'	System	09 Sep 2020 23:44:17

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '09 Sep 2020 16:27'	System	09 Sep 2020 23:13:18

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '09 Sep 2020 18:57'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:26:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
Data entry locked.	System	09 Sep 2020 23:13:18
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:26:54

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:26:54**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03

US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:26:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03



US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:26:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:26:54**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:26:54**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03

US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:26:54

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 16:22:03

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '09 Sep 2020 19:52'	System	09 Sep 2020 23:13:18

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 23:13:18

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
Data entry locked.	System	09 Sep 2020 23:13:18
User entered 'Day 2'	System	09 Sep 2020 23:13:18



US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:26:54

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-10T19:05:08', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '04def1e8-b13e-4e44-ba66-fb4c4150c06e'	System	11 Sep 2020 02:05:31
User entered 'None (0)'	System	11 Sep 2020 02:05:31

US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:26:54

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-10T19:05:11', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '04def1e8-b13e-4e44-ba66-fb4c4150c06e'	System	11 Sep 2020 02:05:31
User entered 'None (0)'	System	11 Sep 2020 02:05:31

US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:26:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-10T19:05:13', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '04def1e8-b13e-4e44-ba66-fb4c4150c06e'	System	11 Sep 2020 02:05:31
User entered 'None (0)'	System	11 Sep 2020 02:05:31

US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:26:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-10T19:05:17', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '04def1e8-b13e-4e44-ba66-fb4c4150c06e' User entered 'None (0)'	System	11 Sep 2020 02:05:31
	System	11 Sep 2020 02:05:31

US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:26:54

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-10T19:05:19', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '04def1e8-b13e-4e44-ba66-fb4c4150c06e'	System	11 Sep 2020 02:05:31
User entered 'None (0)'	System	11 Sep 2020 02:05:31

US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:26:54

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-10T19:05:22', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '04def1e8-b13e-4e44-ba66-fb4c4150c06e'	System	11 Sep 2020 02:05:31
User entered 'None (0)'	System	11 Sep 2020 02:05:31

US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:26:54

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 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-10T19:05:25', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '04def1e8-b13e-4e44-ba66-fb4c4150c06e'	System	11 Sep 2020 02:05:31
User entered 'No (N)'	System	11 Sep 2020 02:05:31

US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:26:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-10T19:05:27', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '04def1e8-b13e-4e44-ba66-fb4c4150c06e'	System	11 Sep 2020 02:05:31
User entered '10 Sep 2020 19:05'	System	11 Sep 2020 02:05:31



**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 23:13:18

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 23:13:18

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
Data entry locked.	System	09 Sep 2020 23:13:18
User entered 'Day 3'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:26:54

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-11T21:44:03', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '253ed19a-7b29-4984-8fea-b73fbc9247d6'	System	12 Sep 2020 04:44:36
User entered 'None (0)'	System	12 Sep 2020 04:44:36

US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:26:54

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-11T21:44:11', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '253ed19a-7b29-4984-8fea-b73fbc9247d6'	System	12 Sep 2020 04:44:36
User entered 'No interference with activity (1)'	System	12 Sep 2020 04:44:36

US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:26:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-11T21:44:15', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '253ed19a-7b29-4984-8fea-b73fbc9247d6'	System	12 Sep 2020 04:44:36
User entered 'None (0)'	System	12 Sep 2020 04:44:36

US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:26:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-11T21:44:17', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '253ed19a-7b29-4984-8fea-b73fbc9247d6'	System	12 Sep 2020 04:44:36
User entered 'None (0)'	System	12 Sep 2020 04:44:36

US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:26:54

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-11T21:44:21', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '253ed19a-7b29-4984-8fea-b73fbc9247d6'	System	12 Sep 2020 04:44:36
User entered 'None (0)'	System	12 Sep 2020 04:44:36



US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:26:54

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-11T21:44:24', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '253ed19a-7b29-4984-8fea-b73fbc9247d6'	System	12 Sep 2020 04:44:36
User entered 'None (0)'	System	12 Sep 2020 04:44:36

US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:26:54

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 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-11T21:44:27', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '253ed19a-7b29-4984-8fea-b73fbc9247d6'	System	12 Sep 2020 04:44:36
User entered 'No (N)'	System	12 Sep 2020 04:44:36

US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:26:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-11T21:44:30', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '253ed19a-7b29-4984-8fea-b73fbc9247d6'	System	12 Sep 2020 04:44:36
User entered '11 Sep 2020 21:44'	System	12 Sep 2020 04:44:36

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 23:13:18

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:26:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
Data entry locked.	System	09 Sep 2020 23:13:18
User entered 'Day 4'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:26:54

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-12T22:31:00', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '4153d14f-7ec0-4d4a-9e56-28da4b6f3f38'	System	13 Sep 2020 05:31:28
User entered 'None (0)'	System	13 Sep 2020 05:31:28

US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:26:54

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-12T22:31:04', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '4153d14f-7ec0-4d4a-9e56-28da4b6f3f38'	System	13 Sep 2020 05:31:28
User entered 'None (0)'	System	13 Sep 2020 05:31:28



US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:26:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-12T22:31:07', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '4153d14f-7ec0-4d4a-9e56-28da4b6f3f38'	System	13 Sep 2020 05:31:28
User entered 'None (0)'	System	13 Sep 2020 05:31:28

US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:26:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-12T22:31:10', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '4153d14f-7ec0-4d4a-9e56-28da4b6f3f38'	System	13 Sep 2020 05:31:28
User entered 'None (0)'	System	13 Sep 2020 05:31:28

US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:26:54

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-12T22:31:13', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '4153d14f-7ec0-4d4a-9e56-28da4b6f3f38'	System	13 Sep 2020 05:31:28
User entered 'None (0)'	System	13 Sep 2020 05:31:28

US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:26:54

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-12T22:31:15', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '4153d14f-7ec0-4d4a-9e56-28da4b6f3f38'	System	13 Sep 2020 05:31:28
User entered 'None (0)'	System	13 Sep 2020 05:31:28

US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:26:54

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 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-12T22:31:19', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '4153d14f-7ec0-4d4a-9e56-28da4b6f3f38'	System	13 Sep 2020 05:31:28
User entered 'No (N)'	System	13 Sep 2020 05:31:28

US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:26:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-12T22:31:22', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '4153d14f-7ec0-4d4a-9e56-28da4b6f3f38'	System	13 Sep 2020 05:31:28
User entered '12 Sep 2020 22:31'	System	13 Sep 2020 05:31:28

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 23:13:18

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 23:13:18



**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
Data entry locked.	System	09 Sep 2020 23:13:18
User entered 'Day 5'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:26:54

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-13T21:46:08', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'aa8afad1-6f66-48cc-9fd4-a5b68587045a'	System	14 Sep 2020 04:46:28
User entered 'None (0)'	System	14 Sep 2020 04:46:28

US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:26:54

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-13T21:46:10', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'aa8afad1-6f66-48cc-9fd4-a5b68587045a'	System	14 Sep 2020 04:46:28
User entered 'None (0)'	System	14 Sep 2020 04:46:28

US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:26:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-13T21:46:13', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'aa8afad1-6f66-48cc-9fd4-a5b68587045a'	System	14 Sep 2020 04:46:28
User entered 'None (0)'	System	14 Sep 2020 04:46:28

US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:26:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-13T21:46:16', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'aa8afad1-6f66-48cc-9fd4-a5b68587045a'	System	14 Sep 2020 04:46:28
User entered 'None (0)'	System	14 Sep 2020 04:46:28

US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:26:54

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-13T21:46:18', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'aa8afad1-6f66-48cc-9fd4-a5b68587045a'	System	14 Sep 2020 04:46:28
User entered 'None (0)'	System	14 Sep 2020 04:46:28

US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:26:54

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-13T21:46:20', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'aa8afad1-6f66-48cc-9fd4-a5b68587045a'	System	14 Sep 2020 04:46:28
User entered 'None (0)'	System	14 Sep 2020 04:46:28

US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:26:54

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 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-13T21:46:24', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'aa8afad1-6f66-48cc-9fd4-a5b68587045a'	System	14 Sep 2020 04:46:28
User entered 'No (N)'	System	14 Sep 2020 04:46:28



US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:26:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-13T21:46:26', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'aa8afad1-6f66-48cc-9fd4-a5b68587045a'	System	14 Sep 2020 04:46:28
User entered '13 Sep 2020 21:46'	System	14 Sep 2020 04:46:28

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 23:13:18

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:26:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
Data entry locked.	System	09 Sep 2020 23:13:18
User entered 'Day 6'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:26:54

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-14T18:02:50', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'd885d68c-cbec-471c-b5dd-b2eceb80e099'	System	15 Sep 2020 01:03:22
User entered 'None (0)'	System	15 Sep 2020 01:03:22

US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:26:54

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-14T18:03:00', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'd885d68c-cbec-471c-b5dd-b2eceb80e099'	System	15 Sep 2020 01:03:22
User entered 'None (0)'	System	15 Sep 2020 01:03:22

US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:26:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-14T18:03:03', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'd885d68c-cbec-471c-b5dd-b2eceb80e099'	System	15 Sep 2020 01:03:22
User entered 'None (0)'	System	15 Sep 2020 01:03:22

US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:26:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-14T18:03:05', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'd885d68c-cbec-471c-b5dd-b2eceb80e099'	System	15 Sep 2020 01:03:22
User entered 'None (0)'	System	15 Sep 2020 01:03:22



US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:26:54

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-14T18:03:08', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'd885d68c-cbec-471c-b5dd-b2eceb80e099'	System	15 Sep 2020 01:03:22
User entered 'None (0)'	System	15 Sep 2020 01:03:22

US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:26:54

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-14T18:03:10', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'd885d68c-cbec-471c-b5dd-b2eceb80e099'	System	15 Sep 2020 01:03:22
User entered 'None (0)'	System	15 Sep 2020 01:03:22

US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:26:54

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 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-14T18:03:14', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'd885d68c-cbec-471c-b5dd-b2eceb80e099'	System	15 Sep 2020 01:03:22
User entered 'No (N)'	System	15 Sep 2020 01:03:22

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-14T18:03:17', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'd885d68c-cbec-471c-b5dd-b2eceb80e099'	System	15 Sep 2020 01:03:22
User entered '14 Sep 2020 18:03'	System	15 Sep 2020 01:03:22

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 23:13:18

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 23:13:18

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
Data entry locked.	System	09 Sep 2020 23:13:18
User entered 'Day 7'	System	09 Sep 2020 23:13:18

US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:26:54

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-15T19:05:46', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'bcefc0e7-5feb-4674-817e-95b082fbe8e8'	System	16 Sep 2020 02:06:12
User entered 'None (0)'	System	16 Sep 2020 02:06:12



US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:26:54

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-15T19:05:54', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'bcefc0e7-5feb-4674-817e-95b082fbe8e8'	System	16 Sep 2020 02:06:12
User entered 'No interference with activity (1)'	System	16 Sep 2020 02:06:12

US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:26:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-15T19:05:51', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'bcefc0e7-5feb-4674-817e-95b082fbe8e8'	System	16 Sep 2020 02:06:12
User entered 'None (0)'	System	16 Sep 2020 02:06:12

US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:26:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-15T19:05:57', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'bcefc0e7-5feb-4674-817e-95b082fbe8e8'	System	16 Sep 2020 02:06:12
User entered 'None (0)'	System	16 Sep 2020 02:06:12

US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:26:54

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-15T19:05:59', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'bcefc0e7-5feb-4674-817e-95b082fbe8e8'	System	16 Sep 2020 02:06:12
User entered 'None (0)'	System	16 Sep 2020 02:06:12

US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:26:54

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-15T19:06:01', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'bcefc0e7-5feb-4674-817e-95b082fbe8e8'	System	16 Sep 2020 02:06:12
User entered 'None (0)'	System	16 Sep 2020 02:06:12

US3732304

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:26:54

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 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-15T19:06:04', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'bcefc0e7-5feb-4674-817e-95b082fbe8e8'	System	16 Sep 2020 02:06:12
User entered 'No (N)'	System	16 Sep 2020 02:06:12

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-15T19:06:06', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'bcefc0e7-5feb-4674-817e-95b082fbe8e8'	System	16 Sep 2020 02:06:12
User entered '15 Sep 2020 19:06'	System	16 Sep 2020 02:06:12

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 23:13:18



**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 23:13:18

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
Data entry locked.	System	16 Sep 2020 02:06:12
User entered 'Day 8'	System	16 Sep 2020 02:06:12

US3732304

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 10 Jun 2021 09:26:54

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-17T10:32:51', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '339342ab-42eb-4e14-9ee6-27dd6a7fb191'	System	17 Sep 2020 17:33:02
User entered 'None (0)'	System	17 Sep 2020 17:33:02

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-17T10:32:56', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '339342ab-42eb-4e14-9ee6-27dd6a7fb191'	System	17 Sep 2020 17:33:02
User entered '17 Sep 2020 10:32'	System	17 Sep 2020 17:33:02

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '16 Sep 2020 12:00'	System	16 Sep 2020 02:06:12

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 02:06:12

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
Data entry locked.	System	16 Sep 2020 02:06:12
User entered 'Day 8'	System	16 Sep 2020 02:06:12

US3732304

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 09:26:54

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 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-17T10:33:01', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'd87c2b6b-48c3-479e-8a80-552a5e2fec03'	System	17 Sep 2020 17:33:09
User entered 'No (N)'	System	17 Sep 2020 17:33:09



**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-09-17T10:33:05', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'd87c2b6b-48c3-479e-8a80-552a5e2fec03'	System	17 Sep 2020 17:33:09
User entered '17 Sep 2020 10:33'	System	17 Sep 2020 17:33:09

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '16 Sep 2020 12:00'	System	16 Sep 2020 02:06:12

**US3732304**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 02:06:12

**US3732304**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:26:54**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:24:43
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:07:46
User entered 'Yes (Y)'	Linda Vega (b) (4)	17 Sep 2020 01:01:24

**US3732304**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:26:54**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:24:43
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:07:46
User entered '16 Sep 2020'	Linda Vega (b) (4) (b) (4)	17 Sep 2020 01:01:24

**US3732304**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:26:54**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:24:43
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:07:46
User entered 'Contact Made (CONTACT MADE)'	Linda Vega (b) (4) (b) (4)	17 Sep 2020 01:01:24

US3732304

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:54

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:24:43
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:07:46
User entered empty.	Linda Vega (b) (4)	17 Sep 2020 01:01:24

**US3732304**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:26:54**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:24:47
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:07:57
User entered 'Yes (Y)'	Linda Vega (b) (4) (b) (4)	17 Sep 2020 01:01:33



**US3732304**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:26:54**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:24:47
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User entered 'l'	System	17 Sep 2020 01:01:33

**US3732304**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:26:54**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:24:53
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:08:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 01:42:25

**US3732304**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:26:54**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:24:53
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:08:36
User entered '23 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 01:42:25

**US3732304**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:26:54**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:24:53
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:08:36
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	24 Sep 2020 01:42:25

US3732304

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:54

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:24:53
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:08:36
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 01:42:25

US3732304

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:26:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:24:57
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:08:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 01:42:14

**US3732304**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:26:54**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:24:57
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User entered 'l'	System	24 Sep 2020 01:42:14

**US3732304**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:26:54**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:06
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:09:37
User entered 'Yes (Y)'	Sylvia Lindholm (b) (4)	30 Sep 2020 17:34:46



US3732304

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:54

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:06
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:09:37
User entered '30 Sep 2020'	Sylvia Lindholm (b) (4)	30 Sep 2020 17:34:46

US3732304

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:06
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:09:37
User entered 'Contact Made (CONTACT MADE)'	Sylvia Lindholm (b) (4)	30 Sep 2020 17:34:46

US3732304

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:54

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:06
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:09:37
User entered empty.	Sylvia Lindholm (b) (4)	30 Sep 2020 17:34:46

US3732304

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:26:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:21
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:09:57
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	01 Oct 2020 19:36:00

**US3732304**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:26:54**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:21
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User entered 'l'	System	01 Oct 2020 19:36:00

**US3732304**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:26:54**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:26
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:10:16
User entered 'Yes (Y)'	Amara Yilmaz (b) (4)	08 Oct 2020 15:54:16

**US3732304**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:26
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:10:16
User entered '07 Oct 2020'	Amara Yilmaz (b) (4) (b) (4)	08 Oct 2020 15:54:16

US3732304

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:26:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:26
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:10:16
User entered 'Clinic (Clinic)'	Amara Yilmaz (b) (4) (b) (4)	08 Oct 2020 15:54:16



**US3732304**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:26:54**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:26
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User entered 'VISIT2'	System	08 Oct 2020 15:54:16

US3732304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:30
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User accepted default value 'Pre-Dose (PREDOSE)'	Amara Yilmaz (b) (4) (b) (4)	08 Oct 2020 15:59:41

US3732304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:30
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:11:00
User entered 'Yes (Y)'	Amara Yilmaz (b) (4) (b) (4)	08 Oct 2020 15:59:41

US3732304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:54

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:30
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:11:00
User entered '07 Oct 2020'	Amara Yilmaz (b) (4) (b) (4)	08 Oct 2020 15:59:41

**US3732304**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:30
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:11:00
User entered '13:25'	Amara Yilmaz (b) (4) (b) (4)	08 Oct 2020 15:59:41

**US3732304**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:30
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User entered '07 Oct 2020 13:25'	System	08 Oct 2020 15:59:41

US3732304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:30
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:11:00
User entered '97.5' F	Amara Yilmaz (b) (4)	08 Oct 2020 15:59:41

US3732304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:30
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:11:00
User entered 'Oral (Oral)'	Amara Yilmaz (b) (4) (b) (4)	08 Oct 2020 15:59:41



US3732304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:30
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:11:00
User entered empty.	Amara Yilmaz (b) (4)	08 Oct 2020 15:59:41

US3732304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:30
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:11:00
User entered '97'	Amara Yilmaz (b) (4) (b) (4)	08 Oct 2020 15:59:41

**US3732304**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:30
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User entered 'bpm'	System	08 Oct 2020 15:59:41

US3732304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:54

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:30
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:11:00
User entered '16'	Amara Yilmaz (b) (4) (b) (4)	08 Oct 2020 15:59:41

**US3732304**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:30
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User entered 'breaths/min'	System	08 Oct 2020 15:59:41

US3732304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:30
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:11:00
User entered '133'	Amara Yilmaz (b) (4) (b) (4)	08 Oct 2020 15:59:41

**US3732304**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:30
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User entered 'mmHg'	System	08 Oct 2020 15:59:41

US3732304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:26:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:30
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:11:00
User entered '89'	Amara Yilmaz (b) (4) (b) (4)	08 Oct 2020 15:59:41



**US3732304**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:30
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User entered 'mmHg'	System	08 Oct 2020 15:59:41

US3732304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:30
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User accepted default value 'Post-Dose (POSTDOSE)'	Amara Yilmaz (b) (4) (b) (4)	08 Oct 2020 15:59:41

US3732304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:30
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:11:00
User entered 'Yes (Y)'	Amara Yilmaz (b) (4) (b) (4)	08 Oct 2020 15:59:41

US3732304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:54

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:30
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:11:00
User entered '07 Oct 2020'	Amara Yilmaz (b) (4) (b) (4)	08 Oct 2020 15:59:41

US3732304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:54

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:30
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:11:00
User entered '14:56'	Amara Yilmaz (b) (4) (b) (4)	08 Oct 2020 15:59:41

**US3732304**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:30
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User entered '07 Oct 2020 14:56'	System	08 Oct 2020 15:59:41

US3732304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:30
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:11:00
User entered '98.7' F	Amara Yilmaz (b) (4)	08 Oct 2020 15:59:41

US3732304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:30
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:11:00
User entered 'Oral (Oral)'	Amara Yilmaz (b) (4) (b) (4)	08 Oct 2020 15:59:41



US3732304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:30
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:11:00
User entered empty.	Amara Yilmaz (b) (4)	08 Oct 2020 15:59:41

**US3732304**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:30
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:11:00
User entered '96'	Amara Yilmaz (b) (4) (b) (4)	08 Oct 2020 15:59:41

**US3732304**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:30
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User entered 'bpm'	System	08 Oct 2020 15:59:41

US3732304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:54

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:30
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:11:00
User entered '15'	Amara Yilmaz (b) (4)	08 Oct 2020 15:59:41

US3732304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:30
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User entered 'breaths/min'	System	08 Oct 2020 15:59:41

US3732304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:30
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:11:00
User entered '135'	Amara Yilmaz (b) (4) (b) (4)	08 Oct 2020 15:59:41

**US3732304**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:30
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User entered 'mmHg'	System	08 Oct 2020 15:59:41

US3732304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:26:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:30
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:11:00
User entered '87'	Amara Yilmaz (b) (4) (b) (4)	08 Oct 2020 15:59:41



**US3732304**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:30
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User entered 'mmHg'	System	08 Oct 2020 15:59:41

US3732304

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:26:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:34
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:11:36
User entered 'Yes (Y)'	Amara Yilmaz (b) (4) (b) (4)	08 Oct 2020 15:54:40

US3732304

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:26:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:34
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:11:36
User entered '07 Oct 2020'	Amara Yilmaz (b) (4)	08 Oct 2020 15:54:40

**US3732304**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:26:54**

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:38
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:12:09
User entered 'Yes (Y)'	Amara Yilmaz (b) (4) (b) (4)	08 Oct 2020 15:56:07

US3732304

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:26:54

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:38
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:12:09
User entered '07 Oct 2020'	Amara Yilmaz (b) (4) (b) (4)	08 Oct 2020 15:56:07

**US3732304**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:26:54**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:38
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:12:09
User entered 'Urine (URINE)'	Amara Yilmaz (b) (4)	08 Oct 2020 15:56:07

US3732304

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:26:54

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:38
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:12:09
User entered 'Negative (NEGATIVE)'	Amara Yilmaz (b) (4)	08 Oct 2020 15:56:07

US3732304

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:26:54

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:38
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:12:09
User entered 'No (N)'	Amara Yilmaz (b) (4)	08 Oct 2020 15:56:07



**US3732304**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:26:54**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:38
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:12:09
User entered empty.	Amara Yilmaz (b) (4)	08 Oct 2020 15:56:07

**US3732304**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:26:54**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:38
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:12:09
User entered empty.	Amara Yilmaz (b) (4)	08 Oct 2020 15:56:07

**US3732304**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:26:54**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:38
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User entered empty.	System	08 Oct 2020 15:56:07

US3732304

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:26:54

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:42
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:12:23
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	07 Oct 2020 21:29:34

US3732304

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:26:54

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:42
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:12:23
User entered empty.	Lauren Arnett (b) (4)	07 Oct 2020 21:29:34

US3732304

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:26:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:42
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:12:23
User entered empty.	Lauren Arnett (b) (4) (b) (4)	07 Oct 2020 21:29:34

**US3732304**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:26:54**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:42
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User entered 'MRNA-1273 OR PLACEBO'	System	07 Oct 2020 21:29:34

US3732304

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:26:54

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:42
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:12:23
User entered '07 Oct 2020'	Lauren Arnett (b) (4)	07 Oct 2020 21:29:34



US3732304

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:26:54

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:42
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:12:23
User entered '14:26'	Lauren Arnett (b) (4)	07 Oct 2020 21:29:34

**US3732304**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:26:54**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:42
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User entered '07 Oct 2020 14:26'	System	07 Oct 2020 21:29:34

US3732304

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:26:54

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:42
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:12:23
User entered 'Right Arm (RIGHT ARM)'	Lauren Arnett (b) (4) (b) (4)	07 Oct 2020 21:29:34

**US3732304**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:26:54**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:42
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:12:23
User entered 'ONCE'	System	07 Oct 2020 21:29:34

US3732304

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:26:54

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:42
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User entered 'INTRAMUSCULAR'	System	07 Oct 2020 21:29:34

US3732304

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:26:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:45
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:12:39
User entered 'Yes (Y)'	Amara Yilmaz (b) (4) (b) (4)	08 Oct 2020 15:55:09

US3732304

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:26:54

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:45
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:12:39
User entered '07 Oct 2020'	Amara Yilmaz (b) (4) (b) (4)	08 Oct 2020 15:55:09

**US3732304**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:26:54**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:45
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:12:39
User entered '14:20'	Amara Yilmaz (b) (4) (b) (4)	08 Oct 2020 15:55:09



**US3732304**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:26:54**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:45
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User entered '07 Oct 2020 14:20'	System	08 Oct 2020 15:55:09

US3732304

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:26:54

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:48
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:12:47
User entered '07 Oct 2020'	Amara Yilmaz (b) (4) (b) (4)	08 Oct 2020 15:55:28

US3732304

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:26:54

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:48
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Amara Yilmaz (b) (4) (b) (4)	08 Oct 2020 15:55:28

US3732304

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:26:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:48
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:12:47
User entered 'Yes (Y)'	Amara Yilmaz (b) (4) (b) (4)	08 Oct 2020 15:55:28

**US3732304**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:48
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:12:47
User entered '13:58'	Amara Yilmaz (b) (4) (b) (4)	08 Oct 2020 15:55:28

**US3732304**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:48
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User entered '07 Oct 2020 13:58'	System	08 Oct 2020 15:55:28

US3732304

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:26:54

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:48
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Amara Yilmaz (b) (4) (b) (4)	08 Oct 2020 15:55:28

US3732304

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:26:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:48
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:12:47
User entered 'No (N)'	Amara Yilmaz (b) (4) (b) (4)	08 Oct 2020 15:55:28



US3732304

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:26:54

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:48
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:12:47
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	08 Oct 2020 15:55:28

**US3732304**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:48
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User entered empty.	System	08 Oct 2020 15:55:28

US3732304

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:26:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:52
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:12:54
User entered 'Yes (Y)'	Amara Yilmaz (b) (4) (b) (4)	08 Oct 2020 15:55:35

**US3732304**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:26:54**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:25:52
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User entered 'I'	System	08 Oct 2020 15:55:35

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:26:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
Data entry locked.	System	07 Oct 2020 21:29:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:26:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-07T15:00:15', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '35808238-29cd-4a7c-90e4-5daf9ac691a5'	System	07 Oct 2020 22:00:50
User entered 'Yes (Y)'	System	07 Oct 2020 22:00:50

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:26:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-07T15:00:21', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '35808238-29cd-4a7c-90e4-5daf9ac691a5'	System	07 Oct 2020 22:00:50
User entered '98.7'	System	07 Oct 2020 22:00:50

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:26:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-07T15:00:25', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '35808238-29cd-4a7c-90e4-5daf9ac691a5'	System	07 Oct 2020 22:00:50
User entered 'No (N)'	System	07 Oct 2020 22:00:50



US3732304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:26:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-07T15:00:45', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '35808238-29cd-4a7c-90e4-5daf9ac691a5'	System	07 Oct 2020 22:00:50
User entered '07 Oct 2020 15:00'	System	07 Oct 2020 22:00:50

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '07 Oct 2020 14:46'	System	07 Oct 2020 21:29:34

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '07 Oct 2020 17:16'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:26:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
Data entry locked.	System	07 Oct 2020 21:29:34
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:26:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-08T11:01:12', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '551924c2-fac9-4fa2-9c88-4e3b5f05e0bb'	System	08 Oct 2020 18:01:35
User entered 'Yes (Y)'	System	08 Oct 2020 18:01:35

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:26:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-08T11:01:20', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '551924c2-fac9-4fa2-9c88-4e3b5f05e0bb'	System	08 Oct 2020 18:01:35
User entered '98.1'	System	08 Oct 2020 18:01:35

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:26:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-08T11:01:24', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '551924c2-fac9-4fa2-9c88-4e3b5f05e0bb'	System	08 Oct 2020 18:01:35
User entered 'No (N)'	System	08 Oct 2020 18:01:35

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-08T11:01:27', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '551924c2-fac9-4fa2-9c88-4e3b5f05e0bb'	System	08 Oct 2020 18:01:35
User entered '08 Oct 2020 11:01'	System	08 Oct 2020 18:01:35



**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '07 Oct 2020 18:11'	System	07 Oct 2020 21:29:34

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 21:29:34

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
Data entry locked.	System	07 Oct 2020 21:29:34
User entered 'Day 2'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:26:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-08T19:31:22', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '98f78f96-e11a-4642-819d-57b756f5033f'	System	09 Oct 2020 02:31:38
User entered 'Yes (Y)'	System	09 Oct 2020 02:31:38

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:26:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-08T19:31:28', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '98f78f96-e11a-4642-819d-57b756f5033f' User entered '98.7'	System	09 Oct 2020 02:31:38
	System	09 Oct 2020 02:31:38

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:26:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-08T19:31:30', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '98f78f96-e11a-4642-819d-57b756f5033f'	System	09 Oct 2020 02:31:38
User entered 'No (N)'	System	09 Oct 2020 02:31:38

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:26:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-08T19:31:34', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '98f78f96-e11a-4642-819d-57b756f5033f'	System	09 Oct 2020 02:31:38
User entered '08 Oct 2020 19:31'	System	09 Oct 2020 02:31:38

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 21:29:34



**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:26:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
Data entry locked.	System	07 Oct 2020 21:29:34
User entered 'Day 3'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:26:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-09T19:45:41', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'f67dd042-f430-42fb-b56d-a1e8754f97e0'	System	10 Oct 2020 02:46:46
User entered 'Yes (Y)'	System	10 Oct 2020 02:46:46

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:26:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-09T19:46:36', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'f67dd042-f430-42fb-b56d-a1e8754f97e0'	System	10 Oct 2020 02:46:46
User entered '99.1'	System	10 Oct 2020 02:46:46

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:26:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-09T19:46:41', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'f67dd042-f430-42fb-b56d-a1e8754f97e0'	System	10 Oct 2020 02:46:46
User entered 'No (N)'	System	10 Oct 2020 02:46:46

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-09T19:46:44', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'f67dd042-f430-42fb-b56d-a1e8754f97e0'	System	10 Oct 2020 02:46:46
User entered '09 Oct 2020 19:46'	System	10 Oct 2020 02:46:46

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 21:29:34

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 21:29:34



US3732304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:26:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
Data entry locked.	System	07 Oct 2020 21:29:34
User entered 'Day 4'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:26:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-10T19:03:04', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '71e57e2d-8181-4e68-9ecf-21e644e6ad58'	System	11 Oct 2020 02:03:20
User entered 'Yes (Y)'	System	11 Oct 2020 02:03:20

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:26:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-10T19:03:09', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '71e57e2d-8181-4e68-9ecf-21e644e6ad58'	System	11 Oct 2020 02:03:20
User entered '99.2'	System	11 Oct 2020 02:03:20

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:26:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-10T19:03:13', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '71e57e2d-8181-4e68-9ecf-21e644e6ad58'	System	11 Oct 2020 02:03:20
User entered 'No (N)'	System	11 Oct 2020 02:03:20

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-10T19:03:17', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '71e57e2d-8181-4e68-9ecf-21e644e6ad58'	System	11 Oct 2020 02:03:20
User entered '10 Oct 2020 19:03'	System	11 Oct 2020 02:03:20

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 21:29:34

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:26:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
Data entry locked.	System	07 Oct 2020 21:29:34
User entered 'Day 5'	System	07 Oct 2020 21:29:34



US3732304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:26:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-12T01:42:32', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '9cee6a99-18bb-42c8-8b50-8e542398e1c9'	System	12 Oct 2020 08:42:45
User entered 'Yes (Y)'	System	12 Oct 2020 08:42:45

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:26:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-12T01:42:35', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '9cee6a99-18bb-42c8-8b50-8e542398e1c9' User entered '98.5'	System	12 Oct 2020 08:42:45
	System	12 Oct 2020 08:42:45

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:26:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-12T01:42:39', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '9cee6a99-18bb-42c8-8b50-8e542398e1c9'	System	12 Oct 2020 08:42:45
User entered 'No (N)'	System	12 Oct 2020 08:42:45

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-12T01:42:41', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '9cee6a99-18bb-42c8-8b50-8e542398e1c9'	System	12 Oct 2020 08:42:45
User entered '12 Oct 2020 01:42'	System	12 Oct 2020 08:42:45

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 21:29:34

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:26:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
Data entry locked.	System	07 Oct 2020 21:29:34
User entered 'Day 6'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:26:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03



US3732304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:26:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:26:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:26:54

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:26:54

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 21:29:34

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 21:29:34

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
Data entry locked.	System	07 Oct 2020 21:29:34
User entered 'Day 7'	System	07 Oct 2020 21:29:34



US3732304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:26:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-13T13:18:08', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'dda373c0-7c18-4c70-a0f9-3eaa27222d66'	System	13 Oct 2020 20:18:24
User entered 'Yes (Y)'	System	13 Oct 2020 20:18:24

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:26:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-13T13:18:14', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'dda373c0-7c18-4c70-a0f9-3eaa27222d66'	System	13 Oct 2020 20:18:24
User entered '98.6'	System	13 Oct 2020 20:18:24

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:26:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-13T13:18:18', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'dda373c0-7c18-4c70-a0f9-3eaa27222d66'	System	13 Oct 2020 20:18:24
User entered 'No (N)'	System	13 Oct 2020 20:18:24

US3732304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:26:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-13T13:18:21', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'dda373c0-7c18-4c70-a0f9-3eaa27222d66'	System	13 Oct 2020 20:18:24
User entered '13 Oct 2020 13:18'	System	13 Oct 2020 20:18:24

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 21:29:34

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 21:29:34

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
Data entry locked.	System	07 Oct 2020 21:29:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:26:54

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 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-07T15:00:54', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '2a9a11e0-860e-46ce-be7c-cd9cf68a031a'	System	07 Oct 2020 22:01:18
User entered 'None (1)'	System	07 Oct 2020 22:01:18



US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:26:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-07T15:00:59', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '2a9a11e0-860e-46ce-be7c-cd9cf68a031a'	System	07 Oct 2020 22:01:18
User entered 'No (N)'	System	07 Oct 2020 22:01:18

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:26:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-07T15:01:02', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '2a9a11e0-860e-46ce-be7c-cd9cf68a031a'	System	07 Oct 2020 22:01:18
User entered 'No (N)'	System	07 Oct 2020 22:01:18

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:26:54

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 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-07T15:01:07', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '2a9a11e0-860e-46ce-be7c-cd9cf68a031a'	System	07 Oct 2020 22:01:18
User entered 'None (1)'	System	07 Oct 2020 22:01:18

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-07T15:01:10', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '2a9a11e0-860e-46ce-be7c-cd9cf68a031a'	System	07 Oct 2020 22:01:18
User entered '07 Oct 2020 15:01'	System	07 Oct 2020 22:01:18

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '07 Oct 2020 14:46'	System	07 Oct 2020 21:29:34

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '07 Oct 2020 17:16'	System	07 Oct 2020 21:29:34

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
Data entry locked.	System	07 Oct 2020 21:29:34
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:26:54

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 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-08T11:01:32', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '80a15ce9-0df3-4300-bb98-d7b0e31d2dab'	System	08 Oct 2020 18:01:46
User entered 'None (1)'	System	08 Oct 2020 18:01:46



US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:26:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-08T11:01:34', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '80a15ce9-0df3-4300-bb98-d7b0e31d2dab'	System	08 Oct 2020 18:01:46
User entered 'No (N)'	System	08 Oct 2020 18:01:46

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:26:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-08T11:01:37', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '80a15ce9-0df3-4300-bb98-d7b0e31d2dab'	System	08 Oct 2020 18:01:46
User entered 'No (N)'	System	08 Oct 2020 18:01:46

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:26:54

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 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-08T11:01:40', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '80a15ce9-0df3-4300-bb98-d7b0e31d2dab'	System	08 Oct 2020 18:01:46
User entered 'None (1)'	System	08 Oct 2020 18:01:46

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-08T11:01:42', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '80a15ce9-0df3-4300-bb98-d7b0e31d2dab'	System	08 Oct 2020 18:01:46
User entered '08 Oct 2020 11:01'	System	08 Oct 2020 18:01:46

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '07 Oct 2020 18:11'	System	07 Oct 2020 21:29:34

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:26:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
Data entry locked.	System	07 Oct 2020 21:29:34
User entered 'Day 2'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:26:54

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 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-08T19:31:50', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'a2e20364-02ef-450d-aea9-5c5a0965bba7'	System	09 Oct 2020 02:32:09
User entered 'Does not interfere with activity (2)'	System	09 Oct 2020 02:32:09



US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:26:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-08T19:31:53', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'a2e20364-02ef-450d-aea9-5c5a0965bba7'	System	09 Oct 2020 02:32:09
User entered 'No (N)'	System	09 Oct 2020 02:32:09

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:26:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-08T19:32:00', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'a2e20364-02ef-450d-aea9-5c5a0965bba7'	System	09 Oct 2020 02:32:09
User entered 'No (N)'	System	09 Oct 2020 02:32:09

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:26:54

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 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-08T19:32:02', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'a2e20364-02ef-450d-aea9-5c5a0965bba7'	System	09 Oct 2020 02:32:09
User entered 'None (1)'	System	09 Oct 2020 02:32:09

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:26:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-08T19:32:06', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'a2e20364-02ef-450d-aea9-5c5a0965bba7'	System	09 Oct 2020 02:32:09
User entered '08 Oct 2020 19:32'	System	09 Oct 2020 02:32:09

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 21:29:34

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:26:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
Data entry locked.	System	07 Oct 2020 21:29:34
User entered 'Day 3'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:26:54

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 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-10T00:00:23', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '5c6fd80f-cde2-4a63-b794-5e2e7c11afbb'	System	10 Oct 2020 07:00:38
User entered 'None (1)'	System	10 Oct 2020 07:00:38



US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:26:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-10T00:00:27', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '5c6fd80f-cde2-4a63-b794-5e2e7c11afbb'	System	10 Oct 2020 07:00:38
User entered 'No (N)'	System	10 Oct 2020 07:00:38

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:26:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-10T00:00:30', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '5c6fd80f-cde2-4a63-b794-5e2e7c11afbb'	System	10 Oct 2020 07:00:38
User entered 'No (N)'	System	10 Oct 2020 07:00:38

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:26:54

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 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-10T00:00:33', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '5c6fd80f-cde2-4a63-b794-5e2e7c11afbb'	System	10 Oct 2020 07:00:38
User entered 'None (1)'	System	10 Oct 2020 07:00:38

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-10T00:00:36', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '5c6fd80f-cde2-4a63-b794-5e2e7c11afbb'	System	10 Oct 2020 07:00:38
User entered '10 Oct 2020 00:00'	System	10 Oct 2020 07:00:38

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 21:29:34

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:26:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
Data entry locked.	System	07 Oct 2020 21:29:34
User entered 'Day 4'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:26:54

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 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-10T19:03:27', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'e14d51a4-b7c6-47ad-a71f-638ac925d51f'	System	11 Oct 2020 02:03:41
User entered 'Does not interfere with activity (2)'	System	11 Oct 2020 02:03:41



US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:26:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-10T19:03:29', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'e14d51a4-b7c6-47ad-a71f-638ac925d51f'	System	11 Oct 2020 02:03:41
User entered 'No (N)'	System	11 Oct 2020 02:03:41

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:26:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-10T19:03:33', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'e14d51a4-b7c6-47ad-a71f-638ac925d51f'	System	11 Oct 2020 02:03:41
User entered 'No (N)'	System	11 Oct 2020 02:03:41

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:26:54

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 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-10T19:03:36', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'e14d51a4-b7c6-47ad-a71f-638ac925d51f'	System	11 Oct 2020 02:03:41
User entered 'None (1)'	System	11 Oct 2020 02:03:41

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-10T19:03:38', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'e14d51a4-b7c6-47ad-a71f-638ac925d51f'	System	11 Oct 2020 02:03:41
User entered '10 Oct 2020 19:03'	System	11 Oct 2020 02:03:41

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 21:29:34

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:26:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
Data entry locked.	System	07 Oct 2020 21:29:34
User entered 'Day 5'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:26:54

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 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-12T01:42:47', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '133db141-4c1e-4a97-9a20-c7af4946bdbc'	System	12 Oct 2020 08:43:03
User entered 'Does not interfere with activity (2)'	System	12 Oct 2020 08:43:03



US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:26:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-12T01:42:49', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '133db141-4c1e-4a97-9a20-c7af4946bdbc'	System	12 Oct 2020 08:43:03
User entered 'No (N)'	System	12 Oct 2020 08:43:03

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:26:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-12T01:42:53', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '133db141-4c1e-4a97-9a20-c7af4946bdbc'	System	12 Oct 2020 08:43:03
User entered 'No (N)'	System	12 Oct 2020 08:43:03

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:26:54

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 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-12T01:42:57', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '133db141-4c1e-4a97-9a20-c7af4946bdbc'	System	12 Oct 2020 08:43:03
User entered 'None (1)'	System	12 Oct 2020 08:43:03

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-12T01:42:59', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '133db141-4c1e-4a97-9a20-c7af4946bdbc'	System	12 Oct 2020 08:43:03
User entered '12 Oct 2020 01:42'	System	12 Oct 2020 08:43:03

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 21:29:34

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 21:29:34

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
Data entry locked.	System	07 Oct 2020 21:29:34
User entered 'Day 6'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:26:54

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 16:22:03



US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:26:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:26:54

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:26:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:26:54

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:26:54

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 16:22:03

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 21:29:34

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 21:29:34



US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:26:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
Data entry locked.	System	07 Oct 2020 21:29:34
User entered 'Day 7'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:26:54

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 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-13T13:18:30', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '7784a56f-fb4f-4861-b57d-bc7ad55efd03'	System	13 Oct 2020 20:18:47
User entered 'Does not interfere with activity (2)'	System	13 Oct 2020 20:18:47

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:26:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-13T13:18:33', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '7784a56f-fb4f-4861-b57d-bc7ad55efd03'	System	13 Oct 2020 20:18:47
User entered 'No (N)'	System	13 Oct 2020 20:18:47

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:26:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-13T13:18:36', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '7784a56f-fb4f-4861-b57d-bc7ad55efd03'	System	13 Oct 2020 20:18:47
User entered 'No (N)'	System	13 Oct 2020 20:18:47

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:26:54

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 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-13T13:18:39', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '7784a56f-fb4f-4861-b57d-bc7ad55efd03'	System	13 Oct 2020 20:18:47
User entered 'None (1)'	System	13 Oct 2020 20:18:47

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-13T13:18:41', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '7784a56f-fb4f-4861-b57d-bc7ad55efd03'	System	13 Oct 2020 20:18:47
User entered '13 Oct 2020 13:18'	System	13 Oct 2020 20:18:47

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 21:29:34

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 21:29:34



**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
Data entry locked.	System	07 Oct 2020 21:29:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:26:54

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-07T15:01:14', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '1aacd0af-759e-4935-8207-584afc5b0b97'	System	07 Oct 2020 22:01:42
User entered 'None (0)'	System	07 Oct 2020 22:01:42

US3732304

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:26:54

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-07T15:01:17', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '1aacd0af-759e-4935-8207-584afc5b0b97'	System	07 Oct 2020 22:01:42
User entered 'None (0)'	System	07 Oct 2020 22:01:42

US3732304

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:26:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-07T15:01:19', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '1aacd0af-759e-4935-8207-584afc5b0b97'	System	07 Oct 2020 22:01:42
User entered 'None (0)'	System	07 Oct 2020 22:01:42

US3732304

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:26:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-07T15:01:21', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '1aacd0af-759e-4935-8207-584afc5b0b97'	System	07 Oct 2020 22:01:42
User entered 'None (0)'	System	07 Oct 2020 22:01:42

US3732304

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:26:54

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-07T15:01:24', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '1aacd0af-759e-4935-8207-584afc5b0b97'	System	07 Oct 2020 22:01:42
User entered 'None (0)'	System	07 Oct 2020 22:01:42

US3732304

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:26:54

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-07T15:01:27', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '1aacd0af-759e-4935-8207-584afc5b0b97'	System	07 Oct 2020 22:01:42
User entered 'None (0)'	System	07 Oct 2020 22:01:42

US3732304

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:26:54

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 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-07T15:01:35', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '1aacd0af-759e-4935-8207-584afc5b0b97'	System	07 Oct 2020 22:01:42
User entered 'No (N)'	System	07 Oct 2020 22:01:42



US3732304

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:26:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-07T15:01:39', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '1aacd0af-759e-4935-8207-584afc5b0b97'	System	07 Oct 2020 22:01:42
User entered '07 Oct 2020 15:01'	System	07 Oct 2020 22:01:42

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '07 Oct 2020 14:46'	System	07 Oct 2020 21:29:34

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '07 Oct 2020 17:16'	System	07 Oct 2020 21:29:34

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
Data entry locked.	System	07 Oct 2020 21:29:34
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:26:54

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-08T11:01:48', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'a72db1c0-8f49-45d8-9748-8a284a571a03'	System	08 Oct 2020 18:02:10
User entered 'None (0)'	System	08 Oct 2020 18:02:10

US3732304

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:26:54

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-08T11:01:51', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'a72db1c0-8f49-45d8-9748-8a284a571a03'	System	08 Oct 2020 18:02:10
User entered 'None (0)'	System	08 Oct 2020 18:02:10

US3732304

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:26:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-08T11:01:53', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'a72db1c0-8f49-45d8-9748-8a284a571a03'	System	08 Oct 2020 18:02:10
User entered 'None (0)'	System	08 Oct 2020 18:02:10

US3732304

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:26:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-08T11:01:54', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'a72db1c0-8f49-45d8-9748-8a284a571a03'	System	08 Oct 2020 18:02:10
User entered 'None (0)'	System	08 Oct 2020 18:02:10



US3732304

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:26:54

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-08T11:01:56', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'a72db1c0-8f49-45d8-9748-8a284a571a03'	System	08 Oct 2020 18:02:10
User entered 'None (0)'	System	08 Oct 2020 18:02:10

US3732304

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:26:54

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-08T11:01:58', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'a72db1c0-8f49-45d8-9748-8a284a571a03'	System	08 Oct 2020 18:02:10
User entered 'None (0)'	System	08 Oct 2020 18:02:10

US3732304

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:26:54

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 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-08T11:02:00', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'a72db1c0-8f49-45d8-9748-8a284a571a03'	System	08 Oct 2020 18:02:10
User entered 'No (N)'	System	08 Oct 2020 18:02:10

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-08T11:02:02', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'a72db1c0-8f49-45d8-9748-8a284a571a03'	System	08 Oct 2020 18:02:10
User entered '08 Oct 2020 11:02'	System	08 Oct 2020 18:02:10

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '07 Oct 2020 18:11'	System	07 Oct 2020 21:29:34

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 21:29:34

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
Data entry locked.	System	07 Oct 2020 21:29:34
User entered 'Day 2'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:26:54

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-08T19:32:10', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'c3695858-c04c-49d4-ab07-82234d7ef759'	System	09 Oct 2020 02:32:32
User entered 'None (0)'	System	09 Oct 2020 02:32:32



US3732304

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:26:54

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-08T19:32:12', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'c3695858-c04c-49d4-ab07-82234d7ef759'	System	09 Oct 2020 02:32:32
User entered 'None (0)'	System	09 Oct 2020 02:32:32

US3732304

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:26:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-08T19:32:14', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'c3695858-c04c-49d4-ab07-82234d7ef759'	System	09 Oct 2020 02:32:32
User entered 'None (0)'	System	09 Oct 2020 02:32:32

US3732304

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:26:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-08T19:32:16', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'c3695858-c04c-49d4-ab07-82234d7ef759'	System	09 Oct 2020 02:32:32
User entered 'None (0)'	System	09 Oct 2020 02:32:32

US3732304

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:26:54

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-08T19:32:17', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'c3695858-c04c-49d4-ab07-82234d7ef759'	System	09 Oct 2020 02:32:32
User entered 'None (0)'	System	09 Oct 2020 02:32:32

US3732304

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:26:54

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-08T19:32:20', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'c3695858-c04c-49d4-ab07-82234d7ef759'	System	09 Oct 2020 02:32:32
User entered 'None (0)'	System	09 Oct 2020 02:32:32

US3732304

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:26:54

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 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-08T19:32:24', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'c3695858-c04c-49d4-ab07-82234d7ef759'	System	09 Oct 2020 02:32:32
User entered 'No (N)'	System	09 Oct 2020 02:32:32

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-08T19:32:28', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'c3695858-c04c-49d4-ab07-82234d7ef759'	System	09 Oct 2020 02:32:32
User entered '08 Oct 2020 19:32'	System	09 Oct 2020 02:32:32

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 21:29:34



**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 21:29:34

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
Data entry locked.	System	07 Oct 2020 21:29:34
User entered 'Day 3'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:26:54

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-10T00:00:40', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '0a9b40ba-79ee-4069-ba9a-cb7844528ff2'	System	10 Oct 2020 07:00:57
User entered 'None (0)'	System	10 Oct 2020 07:00:57

US3732304

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:26:54

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-10T00:00:41', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '0a9b40ba-79ee-4069-ba9a-cb7844528ff2'	System	10 Oct 2020 07:00:57
User entered 'None (0)'	System	10 Oct 2020 07:00:57

US3732304

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:26:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-10T00:00:43', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '0a9b40ba-79ee-4069-ba9a-cb7844528ff2'	System	10 Oct 2020 07:00:57
User entered 'None (0)'	System	10 Oct 2020 07:00:57

US3732304

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:26:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-10T00:00:45', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '0a9b40ba-79ee-4069-ba9a-cb7844528ff2'	System	10 Oct 2020 07:00:57
User entered 'None (0)'	System	10 Oct 2020 07:00:57

US3732304

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:26:54

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-10T00:00:47', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '0a9b40ba-79ee-4069-ba9a-cb7844528ff2'	System	10 Oct 2020 07:00:57
User entered 'None (0)'	System	10 Oct 2020 07:00:57

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:26:54**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-10T00:00:48', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '0a9b40ba-79ee-4069-ba9a-cb7844528ff2'	System	10 Oct 2020 07:00:57
User entered 'None (0)'	System	10 Oct 2020 07:00:57



US3732304

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:26:54

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 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-10T00:00:51', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '0a9b40ba-79ee-4069-ba9a-cb7844528ff2'	System	10 Oct 2020 07:00:57
User entered 'No (N)'	System	10 Oct 2020 07:00:57

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-10T00:00:53', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '0a9b40ba-79ee-4069-ba9a-cb7844528ff2'	System	10 Oct 2020 07:00:57
User entered '10 Oct 2020 00:00'	System	10 Oct 2020 07:00:57

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 21:29:34

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 21:29:34

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
Data entry locked.	System	07 Oct 2020 21:29:34
User entered 'Day 4'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:26:54

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-10T19:03:42', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '1b958527-c625-4174-99e8-b6cd9e86990f'	System	11 Oct 2020 02:03:58
User entered 'None (0)'	System	11 Oct 2020 02:03:58

US3732304

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:26:54

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-10T19:03:44', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '1b958527-c625-4174-99e8-b6cd9e86990f'	System	11 Oct 2020 02:03:58
User entered 'None (0)'	System	11 Oct 2020 02:03:58

US3732304

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:26:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-10T19:03:46', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '1b958527-c625-4174-99e8-b6cd9e86990f'	System	11 Oct 2020 02:03:58
User entered 'None (0)'	System	11 Oct 2020 02:03:58



US3732304

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:26:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-10T19:03:47', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '1b958527-c625-4174-99e8-b6cd9e86990f'	System	11 Oct 2020 02:03:58
User entered 'None (0)'	System	11 Oct 2020 02:03:58

US3732304

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:26:54

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-10T19:03:49', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '1b958527-c625-4174-99e8-b6cd9e86990f'	System	11 Oct 2020 02:03:58
User entered 'None (0)'	System	11 Oct 2020 02:03:58

US3732304

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:26:54

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-10T19:03:51', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '1b958527-c625-4174-99e8-b6cd9e86990f'	System	11 Oct 2020 02:03:58
User entered 'None (0)'	System	11 Oct 2020 02:03:58

US3732304

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:26:54

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 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-10T19:03:53', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '1b958527-c625-4174-99e8-b6cd9e86990f'	System	11 Oct 2020 02:03:58
User entered 'No (N)'	System	11 Oct 2020 02:03:58

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-10T19:03:55', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '1b958527-c625-4174-99e8-b6cd9e86990f' User entered '10 Oct 2020 19:03'	System	11 Oct 2020 02:03:58
	System	11 Oct 2020 02:03:58

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 21:29:34

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 21:29:34

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
Data entry locked.	System	07 Oct 2020 21:29:34
User entered 'Day 5'	System	07 Oct 2020 21:29:34



US3732304

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:26:54

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-12T01:43:03', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'c6df317b-5e1b-4710-88cb-6a495ef30949'	System	12 Oct 2020 08:43:23
User entered 'None (0)'	System	12 Oct 2020 08:43:23

US3732304

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:26:54

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-12T01:43:06', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'c6df317b-5e1b-4710-88cb-6a495ef30949'	System	12 Oct 2020 08:43:23
User entered 'None (0)'	System	12 Oct 2020 08:43:23

US3732304

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:26:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-12T01:43:08', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'c6df317b-5e1b-4710-88cb-6a495ef30949'	System	12 Oct 2020 08:43:23
User entered 'None (0)'	System	12 Oct 2020 08:43:23

US3732304

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:26:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-12T01:43:11', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'c6df317b-5e1b-4710-88cb-6a495ef30949'	System	12 Oct 2020 08:43:23
User entered 'None (0)'	System	12 Oct 2020 08:43:23

US3732304

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:26:54

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-12T01:43:13', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'c6df317b-5e1b-4710-88cb-6a495ef30949'	System	12 Oct 2020 08:43:23
User entered 'None (0)'	System	12 Oct 2020 08:43:23

US3732304

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:26:54

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-12T01:43:14', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'c6df317b-5e1b-4710-88cb-6a495ef30949'	System	12 Oct 2020 08:43:23
User entered 'None (0)'	System	12 Oct 2020 08:43:23

US3732304

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:26:54

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 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-12T01:43:17', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'c6df317b-5e1b-4710-88cb-6a495ef30949'	System	12 Oct 2020 08:43:23
User entered 'No (N)'	System	12 Oct 2020 08:43:23

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-12T01:43:20', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'c6df317b-5e1b-4710-88cb-6a495ef30949'	System	12 Oct 2020 08:43:23
User entered '12 Oct 2020 01:43'	System	12 Oct 2020 08:43:23



**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 21:29:34

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 21:29:34

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
Data entry locked.	System	07 Oct 2020 21:29:34
User entered 'Day 6'	System	07 Oct 2020 21:29:34

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:26:54**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:26:54**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03

US3732304

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:26:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03

US3732304

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:26:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:26:54**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03



**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:26:54**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03

US3732304

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:26:54

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 16:22:03

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 21:29:34

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 21:29:34

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
Data entry locked.	System	07 Oct 2020 21:29:34
User entered 'Day 7'	System	07 Oct 2020 21:29:34

US3732304

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:26:54

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-13T13:18:45', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '380060b5-b7b3-4ef7-8a05-69e0c0073474'	System	13 Oct 2020 20:19:05
User entered 'None (0)'	System	13 Oct 2020 20:19:05

US3732304

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:26:54

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-13T13:18:47', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '380060b5-b7b3-4ef7-8a05-69e0c0073474'	System	13 Oct 2020 20:19:05
User entered 'None (0)'	System	13 Oct 2020 20:19:05



US3732304

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:26:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-13T13:18:50', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '380060b5-b7b3-4ef7-8a05-69e0c0073474'	System	13 Oct 2020 20:19:05
User entered 'None (0)'	System	13 Oct 2020 20:19:05

US3732304

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:26:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-13T13:18:52', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '380060b5-b7b3-4ef7-8a05-69e0c0073474' User entered 'None (0)'	System	13 Oct 2020 20:19:05
	System	13 Oct 2020 20:19:05

US3732304

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:26:54

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-13T13:18:54', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '380060b5-b7b3-4ef7-8a05-69e0c0073474'	System	13 Oct 2020 20:19:05
User entered 'None (0)'	System	13 Oct 2020 20:19:05

US3732304

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:26:54

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-13T13:18:56', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '380060b5-b7b3-4ef7-8a05-69e0c0073474'	System	13 Oct 2020 20:19:05
User entered 'None (0)'	System	13 Oct 2020 20:19:05

US3732304

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:26:54

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 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-13T13:18:58', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '380060b5-b7b3-4ef7-8a05-69e0c0073474'	System	13 Oct 2020 20:19:05
User entered 'No (N)'	System	13 Oct 2020 20:19:05

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-13T13:19:00', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '380060b5-b7b3-4ef7-8a05-69e0c0073474'	System	13 Oct 2020 20:19:05
User entered '13 Oct 2020 13:19'	System	13 Oct 2020 20:19:05

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 21:29:34

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 21:29:34



US3732304

Folder: Diary Dose 2 (1)

Form: Injection Pain\_Day(8)

Generated On: 10 Jun 2021 09:26:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
Data entry locked.	System	13 Oct 2020 20:18:47
User entered 'Day 8'	System	13 Oct 2020 20:18:47

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Pain\_Day(8)

Generated On: 10 Jun 2021 09:26:54

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 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-14T23:07:51', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'fa1704f9-f277-443c-a7de-c33990d6a5be'	System	15 Oct 2020 06:08:05
User entered 'Does not interfere with activity (2)'	System	15 Oct 2020 06:08:05

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Injection Pain\_Day(8)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-14T23:07:59', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'fa1704f9-f277-443c-a7de-c33990d6a5be'	System	15 Oct 2020 06:08:05
User entered '14 Oct 2020 23:07'	System	15 Oct 2020 06:08:05

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Injection Pain\_Day(8)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 20:18:47

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Injection Pain\_Day(8)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 20:18:47

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Injection Pain\_Day(9)**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
Data entry locked.	System	13 Oct 2020 20:18:47
User entered 'Day 9'	System	13 Oct 2020 20:18:47

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Pain\_Day(9)

Generated On: 10 Jun 2021 09:26:54

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 16:22:03

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Injection Pain\_Day(9)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03



**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Injection Pain\_Day(9)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 20:18:47

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Injection Pain\_Day(9)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 20:18:47

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Injection Pain\_Day(10)**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
Data entry locked.	System	15 Oct 2020 06:08:05
User entered 'Day 10'	System	15 Oct 2020 06:08:05

US3732304

Folder: Diary Dose 2 (1)

Form: Injection Pain\_Day(10)

Generated On: 10 Jun 2021 09:26:54

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 16:22:03

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Injection Pain\_Day(10)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Injection Pain\_Day(10)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '16 Oct 2020 12:00'	System	15 Oct 2020 06:08:05

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Injection Pain\_Day(10)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '17 Oct 2020 11:59'	System	15 Oct 2020 06:08:05

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
Data entry locked.	System	13 Oct 2020 20:18:47
User entered 'Day 8'	System	13 Oct 2020 20:18:47



US3732304

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 09:26:54

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 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-14T23:08:03', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '88866545-2951-4597-a82b-8363e527417f'	System	15 Oct 2020 06:08:12
User entered 'No (N)'	System	15 Oct 2020 06:08:12

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2020-10-14T23:08:06', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '88866545-2951-4597-a82b-8363e527417f' User entered '14 Oct 2020 23:08'	System	15 Oct 2020 06:08:12
	System	15 Oct 2020 06:08:12

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 20:18:47

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 20:18:47

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
Data entry locked.	System	13 Oct 2020 20:18:47
User entered 'Day 9'	System	13 Oct 2020 20:18:47

US3732304

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 09:26:54

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 16:22:03

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 20:18:47



**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(9)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 20:18:47

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(10)**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
Data entry locked.	System	15 Oct 2020 06:08:05
User entered 'Day 10'	System	15 Oct 2020 06:08:05

US3732304

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(10)

Generated On: 10 Jun 2021 09:26:54

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 16:22:03

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(10)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(10)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '16 Oct 2020 12:00'	System	15 Oct 2020 06:08:05

**US3732304**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(10)**

**Generated On: 10 Jun 2021 09:26:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:22:03
User entered '17 Oct 2020 11:59'	System	15 Oct 2020 06:08:05

US3732304

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:26:02
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:13:48
User entered 'Yes (Y)'	Sylvia Lindholm (b) (4)	16 Oct 2020 01:36:40

US3732304

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:54

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:26:02
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:13:48
User entered '15 Oct 2020'	Sylvia Lindholm (b) (4)	16 Oct 2020 01:36:40



US3732304

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:26:02
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:13:48
User entered 'Contact Made (CONTACT MADE)'	Sylvia Lindholm (b) (4)	16 Oct 2020 01:36:40

US3732304

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:54

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:26:02
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:13:48
User entered empty.	Sylvia Lindholm (b) (4)	16 Oct 2020 01:36:40

US3732304

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:26:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:26:05
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:13:58
User entered 'Yes (Y)'	Sylvia Lindholm (b) (4)	16 Oct 2020 01:36:46

**US3732304**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:26:54**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:26:05
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User entered 'l'	System	16 Oct 2020 01:36:46

**US3732304**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:26:54**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:26:10
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:14:31
User entered 'Yes (Y)'	Linda Vega (b) (4)	21 Oct 2020 22:36:37

US3732304

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:54

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:26:10
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:14:31
User entered '21 Oct 2020'	Linda Vega (b) (4)	21 Oct 2020 22:36:37

US3732304

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:26:10
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:14:31
User entered 'Contact Made (CONTACT MADE)'	Linda Vega (b) (4) (b) (4)	21 Oct 2020 22:36:37

US3732304

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:54

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:26:10
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:14:31
User entered empty.	Linda Vega (b) (4)	21 Oct 2020 22:36:37



US3732304

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:26:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:26:13
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:14:37
User entered 'Yes (Y)'	Linda Vega (b) (4) (b) (4)	21 Oct 2020 22:36:41

**US3732304**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:26:54**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:26:13
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User entered 'l'	System	21 Oct 2020 22:36:41

US3732304

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:26:18
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User closed query 'Per GCL Lab Reconciliation: Per GCL, there is an immunogenicity sample collected on 03DEC2020 for the Visit 3 Day 57 Visit, however, there is no data recorded for the Visit 3 Day 57 Visit. Please clarify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 17:33:40
Query 'Per GCL Lab Reconciliation: Per GCL, there is an immunogenicity sample collected on 03DEC2020 for the Visit 3 Day 57 Visit, however, there is no data recorded for the Visit 3 Day 57 Visit. Please clarify and update as appropriate. ' answered with 'data has been entered ' (Site from DM).	Amara Yilmaz (b) (4)	08 Jan 2021 18:48:44
User opened query 'Per GCL Lab Reconciliation: Per GCL, there is an immunogenicity sample collected on 03DEC2020 for the Visit 3 Day 57 Visit, however, there is no data recorded for the Visit 3 Day 57 Visit. Please clarify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 17:42:56
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:14:48
User entered 'Yes (Y)'	Linda Vega (b) (4)	28 Oct 2020 18:13:55

US3732304

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:54

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:26:18
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:14:48
User entered '28 Oct 2020'	Linda Vega (b) (4) (b) (4)	28 Oct 2020 18:13:55

US3732304

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:26:18
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:14:48
User entered 'Contact Made (CONTACT MADE)'	Linda Vega (b) (4)	28 Oct 2020 18:13:55

US3732304

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:54

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:26:18
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:14:48
User entered empty.	Linda Vega (b) (4)	28 Oct 2020 18:13:55

US3732304

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:26:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:26:22
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:15:04
User entered 'Yes (Y)'	Linda Vega (b) (4)	28 Oct 2020 18:13:46

**US3732304**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:26:54**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:26:22
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User entered 'l'	System	28 Oct 2020 18:13:46



**US3732304**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:26:54**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:26:26
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:38:44
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
User entered 'Yes (Y)'	(b) (4) Gordon Bovee (b) (4) (b) (4)	08 Jan 2021 18:32:06

US3732304

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:26:54

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:26:26
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:38:44
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
User closed query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	15 Jan 2021 13:11:05
Query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'deviation recorded. Subject was hospitalized' (Site from System).	Gordon Bovee (b) (4)	08 Jan 2021 18:55:44
User opened query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	08 Jan 2021 18:32:06
User entered '03 Dec 2020'	Gordon Bovee (b) (4)	08 Jan 2021 18:32:06

**US3732304**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:26:26
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:38:44
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
User entered 'Clinic (Clinic)'	(b) (4) Gordon Bovee (b) (4) (b) (4)	08 Jan 2021 18:32:06

**US3732304**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:26:54**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:26:26
Data hard locked.		29 Mar 2021 09:11:10
User entered 'VISIT3'	System	08 Jan 2021 18:32:06

**US3732304**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:26:54**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:26:30
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:50:30
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
User entered 'Yes (Y)'	(b) (4) Gordon Bovee (b) (4) (b) (4)	08 Jan 2021 18:33:37

US3732304

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:26:30
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:50:30
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
User entered '03 Dec 2020'	(b) (4) Gordon Bovee (b) (4) (b) (4)	08 Jan 2021 18:33:37

**US3732304**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:26:54**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:26:30
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:50:30
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
User entered '13:40'	(b) (4) Gordon Bovee (b) (4) (b) (4)	08 Jan 2021 18:33:37

**US3732304**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:26:54**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:26:30
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User entered '03 Dec 2020 13:40'	System	08 Jan 2021 18:33:37



**US3732304**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:26:54**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:26:30
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:50:30
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
User entered '98.7' F	(b) (4) Gordon Bovee (b) (4) (b) (4)	08 Jan 2021 18:33:37

**US3732304**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:26:54**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:26:30
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:50:30
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
User entered 'Oral (Oral)'	(b) (4) Gordon Bovee (b) (4) (b) (4)	08 Jan 2021 18:33:37

**US3732304**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:26:54**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:26:30
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:50:30
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
User entered empty.	(b) (4) Gordon Bovee (b) (4) (b) (4)	08 Jan 2021 18:33:37

**US3732304**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:26:54**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:26:30
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:50:30
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
User entered '89'	(b) (4) Gordon Bovee (b) (4) (b) (4)	08 Jan 2021 18:33:37

**US3732304**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:26:54**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:26:30
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User entered 'bpm'	System	08 Jan 2021 18:33:37

US3732304

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:54

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:26:30
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:50:30
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
User entered '16'	(b) (4) Gordon Bovee (b) (4) (b) (4)	08 Jan 2021 18:33:37

**US3732304**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:26:54**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:26:30
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User entered 'breaths/min'	System	08 Jan 2021 18:33:37

US3732304

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:26:30
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:50:30
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
User entered '123'	(b) (4) Gordon Bovee (b) (4) (b) (4)	08 Jan 2021 18:33:37



**US3732304**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:26:54**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:26:30
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User entered 'mmHg'	System	08 Jan 2021 18:33:37

US3732304

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:26:30
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:50:30
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
User closed query 'Diastolic Blood Pressure reported is out of range > 100 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)	08 Jan 2021 21:10:05
Query 'Diastolic Blood Pressure reported is out of range > 100 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)	08 Jan 2021 18:42:53
User opened query 'Diastolic Blood Pressure reported System is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		08 Jan 2021 18:33:37
User entered '101'	Gordon Bovee (b) (4) (b) (4)	08 Jan 2021 18:33:37

**US3732304**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:26:54**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:26:30
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User entered 'mmHg'	System	08 Jan 2021 18:33:37

**US3732304**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:26:54**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:26:30
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10

**US3732304**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:26:54**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:26:30
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10

US3732304

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:26:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:26:34
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:50:16
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
User entered 'Yes (Y)'	(b) (4) Gordon Bovee (b) (4) (b) (4)	08 Jan 2021 18:36:28

**US3732304**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:26:54**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:26:34
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:50:16
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
User entered '03 Dec 2020'	(b) (4) Gordon Bovee (b) (4) (b) (4)	08 Jan 2021 18:36:28

US3732304

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:26:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:26:38
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:50:34
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
User entered 'Yes (Y)'	(b) (4) Gordon Bovee (b) (4) (b) (4)	08 Jan 2021 18:42:35



US3732304

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:26:54

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:26:38
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:50:34
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
User entered '03 Dec 2020'	(b) (4) Gordon Bovee (b) (4) (b) (4)	08 Jan 2021 18:42:35

**US3732304**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:26:54**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:26:38
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:50:34
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
User entered '14:35'	(b) (4) Gordon Bovee (b) (4) (b) (4)	08 Jan 2021 18:42:35

**US3732304**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:26:54**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:26:38
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User entered '03 Dec 2020 14:35'	System	08 Jan 2021 18:42:35

US3732304

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:26:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:26:42
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 23:13:12
User entered 'Yes (Y)'	Linda Vega (b) (4) (b) (4)	02 Dec 2020 20:26:33

**US3732304**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:26:54**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:26:42
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User entered 'l'	System	02 Dec 2020 20:26:33

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:53:31
Data entry locked.	System	09 Sep 2020 23:13:18
User entered 'Day 64'	System	09 Sep 2020 23:13:18

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[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)	24 Apr 2021 04:36:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Have you been exposed to someone with 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)	24 Apr 2021 04:36:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:53:31



**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Fever \(Temperature  \$\geq\$  100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:53:31



**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:53:31



**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:53:31
Data entry locked.	System	09 Sep 2020 23:13:18
User entered '09 Nov 2020 00:01'	System	09 Sep 2020 23:13:18



**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:53:31
Data entry locked.	System	09 Sep 2020 23:13:18
User entered '13 Nov 2020 23:59'	System	09 Sep 2020 23:13:18

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:53:31
Data entry locked.	System	09 Sep 2020 23:13:18
User entered 'Day 71'	System	09 Sep 2020 23:13:18

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[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)	24 Apr 2021 04:36:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Have you been exposed to someone with 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)	24 Apr 2021 04:36:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:53:31



**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:53:31



**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:53:31



**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:53:31
Data entry locked.	System	09 Sep 2020 23:13:18
User entered '16 Nov 2020 00:01'	System	09 Sep 2020 23:13:18

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:36
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:53:31
Data entry locked.	System	09 Sep 2020 23:13:18
User entered '20 Nov 2020 23:59'	System	09 Sep 2020 23:13:18

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '20 Nov 2020 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '24 Nov 2020 23:59'	System	20 Nov 2020 06:53:31



**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '27 Nov 2020 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '01 Dec 2020 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '04 Dec 2020 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '08 Dec 2020 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '11 Dec 2020 00:01'	System	20 Nov 2020 06:53:31



**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '15 Dec 2020 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 06:53:31



**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[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 (ee54f00ecea9d6bb)', Time: '2021-01-05T14:31:28', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'cccb7cff-66ab-4ed8-9b91-f2fec84c8df2'	System	05 Jan 2021 22:32:06
User entered 'No (N)'	System	05 Jan 2021 22:32:06

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Have you been exposed to someone with 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 (ee54f00ecea9d6bb)', Time: '2021-01-05T14:31:48', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'cccb7cff-66ab-4ed8-9b91-f2fec84c8df2'	System	05 Jan 2021 22:32:06
User entered 'No (N)'	System	05 Jan 2021 22:32:06

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2021-01-05T14:31:58', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'cccb7cff-66ab-4ed8-9b91-f2fec84c8df2'	System	05 Jan 2021 22:32:06
User entered '05 Jan 2021 14:31:58'	System	05 Jan 2021 22:32:06

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 06:53:31



**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[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 (ee54f00ecea9d6bb)', Time: '2021-01-16T07:20:04', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '7234cc33-c42e-47ff-9425-7b0f3b595493'	System	16 Jan 2021 15:20:24
User entered 'No (N)'	System	16 Jan 2021 15:20:24

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

Have you been exposed to someone with 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 (ee54f00ecea9d6bb)', Time: '2021-01-16T07:20:14', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '7234cc33-c42e-47ff-9425-7b0f3b595493'	System	16 Jan 2021 15:20:24
User entered 'No (N)'	System	16 Jan 2021 15:20:24

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2021-01-16T07:20:22', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '7234cc33-c42e-47ff-9425-7b0f3b595493' User entered '16 Jan 2021 07:20:22'	System	16 Jan 2021 15:20:24
	System	16 Jan 2021 15:20:24

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[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 (ee54f00ecea9d6bb)', Time: '2021-01-25T21:57:04', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '98dbc3b0-f2a1-4181-b328-4250d760631a'	System	26 Jan 2021 05:57:19
User entered 'No (N)'	System	26 Jan 2021 05:57:19



**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

Have you been exposed to someone with 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 (ee54f00ecea9d6bb)', Time: '2021-01-25T21:57:11', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '98dbc3b0-f2a1-4181-b328-4250d760631a'	System	26 Jan 2021 05:57:19
User entered 'No (N)'	System	26 Jan 2021 05:57:19

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2021-01-25T21:57:15', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '98dbc3b0-f2a1-4181-b328-4250d760631a' User entered '25 Jan 2021 21:57:15'	System	26 Jan 2021 05:57:19

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '22 Jan 2021 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '26 Jan 2021 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[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 (ee54f00ecea9d6bb)', Time: '2021-01-31T10:42:15', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '189df543-5ce9-4384-b742-928afd6804c8'	System	31 Jan 2021 18:42:27
User entered 'No (N)'	System	31 Jan 2021 18:42:27

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

Have you been exposed to someone with 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 (ee54f00ecea9d6bb)', Time: '2021-01-31T10:42:18', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '189df543-5ce9-4384-b742-928afd6804c8'	System	31 Jan 2021 18:42:27
User entered 'No (N)'	System	31 Jan 2021 18:42:27

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2021-01-31T10:42:24', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '189df543-5ce9-4384-b742-928afd6804c8'	System	31 Jan 2021 18:42:27
User entered '31 Jan 2021 10:42:24'	System	31 Jan 2021 18:42:27



**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '29 Jan 2021 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '02 Feb 2021 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[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 (ee54f00ecea9d6bb)', Time: '2021-02-05T16:39:26', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '131be903-0fbf-49fc-83d5-725af7662e24'	System	06 Feb 2021 00:39:38
User entered 'No (N)'	System	06 Feb 2021 00:39:38

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

Have you been exposed to someone with 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 (ee54f00ecea9d6bb)', Time: '2021-02-05T16:39:30', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '131be903-0fbf-49fc-83d5-725af7662e24'	System	06 Feb 2021 00:39:38
User entered 'No (N)'	System	06 Feb 2021 00:39:38

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2021-02-05T16:39:34', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '131be903-0fbf-49fc-83d5-725af7662e24'	System	06 Feb 2021 00:39:38
User entered '05 Feb 2021 16:39:34'	System	06 Feb 2021 00:39:38

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '05 Feb 2021 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '09 Feb 2021 23:59'	System	20 Nov 2020 06:53:31



**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[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 (ee54f00ecea9d6bb)', Time: '2021-02-12T09:56:30', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'c7532933-dcef-4d29-b567-12259082ae42'	System	12 Feb 2021 17:56:41
User entered 'No (N)'	System	12 Feb 2021 17:56:41

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

Have you been exposed to someone with 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 (ee54f00ecea9d6bb)', Time: '2021-02-12T09:56:33', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'c7532933-dcef-4d29-b567-12259082ae42'	System	12 Feb 2021 17:56:41
User entered 'No (N)'	System	12 Feb 2021 17:56:41

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2021-02-12T09:56:38', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'c7532933-dcef-4d29-b567-12259082ae42'	System	12 Feb 2021 17:56:41
User entered '12 Feb 2021 09:56:38'	System	12 Feb 2021 17:56:41

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '12 Feb 2021 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '16 Feb 2021 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[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 (ee54f00ecea9d6bb)', Time: '2021-02-19T15:57:30', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '91f1b6fc-a1d1-47e1-a3ae-327a300a0ae9'	System	19 Feb 2021 23:57:39
User entered 'No (N)'	System	19 Feb 2021 23:57:39



**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

Have you been exposed to someone with 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 (ee54f00ecea9d6bb)', Time: '2021-02-19T15:57:33', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '91f1b6fc-a1d1-47e1-a3ae-327a300a0ae9'	System	19 Feb 2021 23:57:39
User entered 'No (N)'	System	19 Feb 2021 23:57:39

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ee54f00ecea9d6bb)', Time: '2021-02-19T15:57:36', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '91f1b6fc-a1d1-47e1-a3ae-327a300a0ae9' User entered '19 Feb 2021 15:57:36'	System	19 Feb 2021 23:57:39
	System	19 Feb 2021 23:57:39

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '19 Feb 2021 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '23 Feb 2021 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '26 Feb 2021 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '02 Mar 2021 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 06:53:31



**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[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 (2b473e32487267a0)', Time: '2021-03-05T13:05:04-08:00', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '5999a7de-398a-402e-b32e-29b2615a9438'	System	05 Mar 2021 21:05:13
User entered 'No (N)'	System	05 Mar 2021 21:05:13

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

Have you been exposed to someone with 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 (2b473e32487267a0)', Time: '2021-03-05T13:05:06-08:00', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '5999a7de-398a-402e-b32e-29b2615a9438'	System	05 Mar 2021 21:05:13
User entered 'No (N)'	System	05 Mar 2021 21:05:13

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b473e32487267a0)', Time: '2021-03-05T13:05:09-08:00', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '5999a7de-398a-402e-b32e-29b2615a9438'	System	05 Mar 2021 21:05:13
User entered '05 Mar 2021 13:05:09'	System	05 Mar 2021 21:05:13

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '05 Mar 2021 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '09 Mar 2021 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[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 (2b473e32487267a0)', Time: '2021-03-16T16:58:34-07:00', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'cd350504-7aa5-4eef-b7a9-04032ac07f86'	System	16 Mar 2021 23:58:47
User entered 'No (N)'	System	16 Mar 2021 23:58:47

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

Have you been exposed to someone with 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 (2b473e32487267a0)', Time: '2021-03-16T16:58:38-07:00', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'cd350504-7aa5-4eef-b7a9-04032ac07f86'	System	16 Mar 2021 23:58:47
User entered 'No (N)'	System	16 Mar 2021 23:58:47



**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b473e32487267a0)', Time: '2021-03-16T16:58:43-07:00', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'cd350504-7aa5-4eef-b7a9-04032ac07f86'	System	16 Mar 2021 23:58:47
User entered '16 Mar 2021 16:58:43'	System	16 Mar 2021 23:58:47

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '12 Mar 2021 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '16 Mar 2021 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[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 (2b473e32487267a0)', Time: '2021-03-19T17:32:13-07:00', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '8e376e53-cc05-4bcf-aefb-276dce45282f' User entered 'No (N)'	System	20 Mar 2021 00:32:31
	System	20 Mar 2021 00:32:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

Have you been exposed to someone with 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 (2b473e32487267a0)', Time: '2021-03-19T17:32:17-07:00', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '8e376e53-cc05-4bcf-aefb-276dce45282f' User entered 'No (N)'	System	20 Mar 2021 00:32:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b473e32487267a0)', Time: '2021-03-19T17:32:23-07:00', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '8e376e53-cc05-4bcf-aefb-276dce45282f' User entered '19 Mar 2021 17:32:23'	System	20 Mar 2021 00:32:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '19 Mar 2021 00:01'	System	20 Nov 2020 06:53:31



**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '23 Mar 2021 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[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 (2b473e32487267a0)', Time: '2021-03-26T17:49:40-07:00', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '88a828cb-b75f-4cc3-a602-176ee0c85028'	System	27 Mar 2021 00:49:56
User entered 'No (N)'	System	27 Mar 2021 00:49:56

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

Have you been exposed to someone with 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 (2b473e32487267a0)', Time: '2021-03-26T17:49:45-07:00', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '88a828cb-b75f-4cc3-a602-176ee0c85028'	System	27 Mar 2021 00:49:56
User entered 'No (N)'	System	27 Mar 2021 00:49:56

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b473e32487267a0)', Time: '2021-03-26T17:49:51-07:00', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '88a828cb-b75f-4cc3-a602-176ee0c85028'	System	27 Mar 2021 00:49:56
User entered '26 Mar 2021 17:49:51'	System	27 Mar 2021 00:49:56

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '26 Mar 2021 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '30 Mar 2021 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 06:53:31



**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '02 Apr 2021 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '06 Apr 2021 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[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 (2b473e32487267a0)', Time: '2021-04-12T03:47:07-07:00', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '5a34de2a-f629-47f0-b71e-183254c61950'	System	12 Apr 2021 10:47:17
User entered 'No (N)'	System	12 Apr 2021 10:47:17

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

Have you been exposed to someone with 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 (2b473e32487267a0)', Time: '2021-04-12T03:47:10-07:00', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '5a34de2a-f629-47f0-b71e-183254c61950'	System	12 Apr 2021 10:47:17
User entered 'No (N)'	System	12 Apr 2021 10:47:17

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b473e32487267a0)', Time: '2021-04-12T03:47:12-07:00', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '5a34de2a-f629-47f0-b71e-183254c61950'	System	12 Apr 2021 10:47:17
User entered '12 Apr 2021 03:47:12'	System	12 Apr 2021 10:47:17

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '09 Apr 2021 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '13 Apr 2021 23:59'	System	20 Nov 2020 06:53:31



**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[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 (2b473e32487267a0)', Time: '2021-04-16T20:06:32-07:00', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'ce9ae12e-82ad-40aa-8c90-ba03b36cc24b'	System	17 Apr 2021 03:06:49
User entered 'No (N)'	System	17 Apr 2021 03:06:49

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

Have you been exposed to someone with 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 (2b473e32487267a0)', Time: '2021-04-16T20:06:35-07:00', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'ce9ae12e-82ad-40aa-8c90-ba03b36cc24b'	System	17 Apr 2021 03:06:49
User entered 'No (N)'	System	17 Apr 2021 03:06:49

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b473e32487267a0)', Time: '2021-04-16T20:06:43-07:00', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'ce9ae12e-82ad-40aa-8c90-ba03b36cc24b'	System	17 Apr 2021 03:06:49
User entered '16 Apr 2021 20:06:43'	System	17 Apr 2021 03:06:49

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '16 Apr 2021 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '20 Apr 2021 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '23 Apr 2021 00:01'	System	20 Nov 2020 06:53:31



**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '27 Apr 2021 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[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 (2b473e32487267a0)', Time: '2021-05-01T20:39:03-07:00', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '7ca75bbd-a2f0-4552-87ed-d166eebdbb27'	System	02 May 2021 03:39:18
User entered 'No (N)'	System	02 May 2021 03:39:18

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Have you been exposed to someone with 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 (2b473e32487267a0)', Time: '2021-05-01T20:39:05-07:00', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '7ca75bbd-a2f0-4552-87ed-d166eebdbb27'	System	02 May 2021 03:39:18
User entered 'No (N)'	System	02 May 2021 03:39:18

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b473e32487267a0)', Time: '2021-05-01T20:39:09-07:00', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: '7ca75bbd-a2f0-4552-87ed-d166eebdbb27'	System	02 May 2021 03:39:18
User entered '01 May 2021 20:39:09'	System	02 May 2021 03:39:18

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '30 Apr 2021 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '04 May 2021 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 06:53:31



**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '07 May 2021 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '11 May 2021 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '14 May 2021 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '18 May 2021 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '21 May 2021 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '25 May 2021 23:59'	System	20 Nov 2020 06:53:31



**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '28 May 2021 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '01 Jun 2021 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '04 Jun 2021 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '08 Jun 2021 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '11 Jun 2021 00:01'	System	20 Nov 2020 06:53:31



**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '15 Jun 2021 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '18 Jun 2021 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '22 Jun 2021 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '25 Jun 2021 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '29 Jun 2021 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 06:53:31



**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '02 Jul 2021 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '06 Jul 2021 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '09 Jul 2021 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '13 Jul 2021 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '16 Jul 2021 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '20 Jul 2021 23:59'	System	20 Nov 2020 06:53:31



**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '23 Jul 2021 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '27 Jul 2021 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '30 Jul 2021 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '03 Aug 2021 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '06 Aug 2021 00:01'	System	20 Nov 2020 06:53:31



**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '10 Aug 2021 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '13 Aug 2021 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '17 Aug 2021 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '20 Aug 2021 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '24 Aug 2021 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 06:53:31



**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '27 Aug 2021 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '31 Aug 2021 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '03 Sep 2021 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '07 Sep 2021 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '10 Sep 2021 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '14 Sep 2021 23:59'	System	20 Nov 2020 06:53:31



**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '17 Sep 2021 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '21 Sep 2021 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '24 Sep 2021 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '28 Sep 2021 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '01 Oct 2021 00:01'	System	20 Nov 2020 06:53:31



**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '05 Oct 2021 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '08 Oct 2021 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '12 Oct 2021 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '15 Oct 2021 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '19 Oct 2021 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 06:53:31



**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '22 Oct 2021 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '26 Oct 2021 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '29 Oct 2021 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '02 Nov 2021 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '05 Nov 2021 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '09 Nov 2021 23:59'	System	20 Nov 2020 06:53:31



**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '12 Nov 2021 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '16 Nov 2021 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '19 Nov 2021 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '23 Nov 2021 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '26 Nov 2021 00:01'	System	20 Nov 2020 06:53:31



**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '30 Nov 2021 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '03 Dec 2021 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '07 Dec 2021 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '10 Dec 2021 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '14 Dec 2021 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 06:53:31



**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '17 Dec 2021 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '21 Dec 2021 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '24 Dec 2021 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '28 Dec 2021 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '31 Dec 2021 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '04 Jan 2022 23:59'	System	20 Nov 2020 06:53:31



**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '07 Jan 2022 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '11 Jan 2022 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '14 Jan 2022 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '18 Jan 2022 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '21 Jan 2022 00:01'	System	20 Nov 2020 06:53:31



**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '25 Jan 2022 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '28 Jan 2022 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '01 Feb 2022 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '04 Feb 2022 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '08 Feb 2022 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 06:53:31



**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '11 Feb 2022 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '15 Feb 2022 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '18 Feb 2022 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '22 Feb 2022 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '25 Feb 2022 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '01 Mar 2022 23:59'	System	20 Nov 2020 06:53:31



**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '04 Mar 2022 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '08 Mar 2022 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '11 Mar 2022 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '15 Mar 2022 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '18 Mar 2022 00:01'	System	20 Nov 2020 06:53:31



**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '22 Mar 2022 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '25 Mar 2022 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '29 Mar 2022 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '01 Apr 2022 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '05 Apr 2022 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 06:53:31



**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '08 Apr 2022 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '12 Apr 2022 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '15 Apr 2022 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '19 Apr 2022 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '22 Apr 2022 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '26 Apr 2022 23:59'	System	20 Nov 2020 06:53:31



**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '29 Apr 2022 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '03 May 2022 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '06 May 2022 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '10 May 2022 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '13 May 2022 00:01'	System	20 Nov 2020 06:53:31



**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '17 May 2022 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '20 May 2022 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '24 May 2022 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '27 May 2022 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '31 May 2022 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 06:53:31



**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '03 Jun 2022 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '07 Jun 2022 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '10 Jun 2022 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '14 Jun 2022 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '17 Jun 2022 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '21 Jun 2022 23:59'	System	20 Nov 2020 06:53:31



**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '24 Jun 2022 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '28 Jun 2022 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '01 Jul 2022 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '05 Jul 2022 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '08 Jul 2022 00:01'	System	20 Nov 2020 06:53:31



**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '12 Jul 2022 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '15 Jul 2022 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '19 Jul 2022 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '22 Jul 2022 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '26 Jul 2022 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 06:53:31



**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '29 Jul 2022 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '02 Aug 2022 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '05 Aug 2022 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '09 Aug 2022 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '12 Aug 2022 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '16 Aug 2022 23:59'	System	20 Nov 2020 06:53:31



**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '19 Aug 2022 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '23 Aug 2022 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '26 Aug 2022 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '30 Aug 2022 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '02 Sep 2022 00:01'	System	20 Nov 2020 06:53:31



**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '06 Sep 2022 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '09 Sep 2022 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '13 Sep 2022 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '16 Sep 2022 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '20 Sep 2022 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 06:53:31



**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '23 Sep 2022 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '27 Sep 2022 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '30 Sep 2022 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '04 Oct 2022 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '07 Oct 2022 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '11 Oct 2022 23:59'	System	20 Nov 2020 06:53:31



**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '14 Oct 2022 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '18 Oct 2022 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '21 Oct 2022 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '25 Oct 2022 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '28 Oct 2022 00:01'	System	20 Nov 2020 06:53:31



**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '01 Nov 2022 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '04 Nov 2022 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '08 Nov 2022 23:59'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '11 Nov 2022 00:01'	System	20 Nov 2020 06:53:31

**US3732304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:26:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:53:31
Amendment Manager: User entered '15 Nov 2022 23:59'	System	20 Nov 2020 06:53:31

US3732304

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:26:54

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b473e32487267a0)', Time: '2021-03-05T13:05:14-08:00', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'd96790d7-428b-4210-85ce-a6ec5e53f876'	System	05 Mar 2021 21:05:22
User entered 'No (N)'	System	05 Mar 2021 21:05:22



**US3732304**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b473e32487267a0)', Time: '2021-03-05T13:05:17-08:00', User OID: 'PatientReportedOutcome (US3732304)', ODM File OID: 'd96790d7-428b-4210-85ce-a6ec5e53f876' User entered '05 Mar 2021 13:05:17'	System	05 Mar 2021 21:05:22
	System	05 Mar 2021 21:05:22

**US3732304**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:26:54**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:26:52
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 23:34:28
User entered 'Yes (Y)'	Linda Vega (b) (4)	02 Dec 2020 20:27:29

US3732304

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:54

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:26:52
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 23:34:28
User entered '02 Dec 2020'	Linda Vega (b) (4)	02 Dec 2020 20:27:29

US3732304

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:26:52
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 23:34:28
User entered 'Contact Made (CONTACT MADE)'	Linda Vega (b) (4)	02 Dec 2020 20:27:29

US3732304

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:54

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:26:52
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 23:34:28
User entered empty.	Linda Vega (b) (4)	02 Dec 2020 20:27:29

US3732304

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:26:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:26:56
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 23:34:34
User entered 'Yes (Y)'	Linda Vega (b) (4) (b) (4)	02 Dec 2020 20:27:36

**US3732304**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:26:54**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:28
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:26:56
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:10
User entered 'l'	System	02 Dec 2020 20:27:36

**US3732304**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:26:54**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:43:10
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:51:48
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered 'Yes (Y)'	(b) (4) Sylvia Lindholm (b) (4)	05 Jan 2021 17:38:16



**US3732304**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:26:54**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:43:10
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:51:48
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered '5 Jan 2021'	(b) (4) Sylvia Lindholm (b) (4)	05 Jan 2021 17:38:16

**US3732304**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:26:54**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:43:10
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:51:48
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sylvia Lindholm (b) (4)	05 Jan 2021 17:38:16

**US3732304**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:26:54**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:43:10
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:51:48
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered empty.	(b) (4) Sylvia Lindholm (b) (4)	05 Jan 2021 17:38:16

**US3732304**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:26:54**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:43:10
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:52:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered 'Yes (Y)'	(b) (4) Sylvia Lindholm (b) (4)	05 Jan 2021 17:38:27

**US3732304**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:26:54**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:43:10
User entered 'I'	System	05 Jan 2021 17:38:27

**US3732304**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:26:54**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:43:10
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:52:42
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered 'Yes (Y)'	(b) (4) Sylvia Lindholm (b) (4)	06 Feb 2021 04:16:38

**US3732304**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:26:54**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:43:10
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:52:42
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered '5 Feb 2021'	(b) (4) Sylvia Lindholm (b) (4)	06 Feb 2021 04:16:38

**US3732304**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:26:54**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:43:10
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:52:42
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sylvia Lindholm (b) (4)	06 Feb 2021 04:16:38



US3732304

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:54

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:43:10
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:52:42
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered empty.	(b) (4) Sylvia Lindholm (b) (4)	06 Feb 2021 04:16:38

**US3732304**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:26:54**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:43:10
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:53:04
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered 'Yes (Y)'	(b) (4) Sylvia Lindholm (b) (4)	06 Feb 2021 04:16:44

**US3732304**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:26:54**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:43:10
User entered 'I'	System	06 Feb 2021 04:16:44

US3732304

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:59:55
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:53:28
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	05 Mar 2021 22:57:38
	(b) (4)	

US3732304

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:26:54

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:59:55
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:53:28
User entered '05 Mar 2021'	Gordon Bovee (b) (4)	05 Mar 2021 22:57:38
	(b) (4)	

**US3732304**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:26:54**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:59:55
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:53:28
User entered 'Contact Made (CONTACT MADE)'	Gordon Bovee (b) (4)	05 Mar 2021 22:57:38
	(b) (4)	

**US3732304**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:26:54**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:59:55
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:53:28
User entered empty.	Gordon Bovee (b) (4)	05 Mar 2021 22:57:38
	(b) (4)	

US3732304

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:26:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:59:55
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:54:04
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	05 Mar 2021 22:57:45
	(b) (4)	



**US3732304**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:26:54**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:59:55
User entered 'I'	System	05 Mar 2021 22:57:45

**US3732304**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:26:54**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:23:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:06:45
User entered 'Yes (Y)'	Gordon Bovee (b) (4) (b) (4)	15 Apr 2021 22:04:46

**US3732304**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:26:54**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:23:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:06:45
User entered '15 Apr 2021' reason for change: Data Entry Error	Gordon Bovee (b) (4)	15 Apr 2021 22:05:24
User entered '14 Apr 2021'	Gordon Bovee (b) (4)	15 Apr 2021 22:04:46

US3732304

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:26:54

[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 22:23:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:06:45
User entered 'Clinic (Clinic)'	Gordon Bovee (b) (4) (b) (4)	15 Apr 2021 22:04:46

**US3732304**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:26:54**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	15 Apr 2021 22:04:46

**US3732304**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:26:54**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:23:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:07:03
User entered 'Yes (Y)'	Gordon Bovee (b) (4) (b) (4)	15 Apr 2021 22:07:24

US3732304

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:23:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:07:03
User entered '15 Apr 2021'	Gordon Bovee (b) (4) (b) (4)	15 Apr 2021 22:07:24

**US3732304**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:26:54**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:23:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:07:03
User entered '11:02'	Gordon Bovee (b) (4) (b) (4)	15 Apr 2021 22:07:24



**US3732304**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:26:54**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '15 Apr 2021 11:02'	System	15 Apr 2021 22:07:24

US3732304

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:54

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:23:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:07:03
User entered '98.8' F	Gordon Bovee (b) (4) (b) (4)	15 Apr 2021 22:07:24

**US3732304**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:26:54**

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:23:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:07:03
User entered 'Oral (Oral)'	Gordon Bovee (b) (4) (b) (4)	15 Apr 2021 22:07:24

**US3732304**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:26:54**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:23:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:07:03
User entered empty.	Gordon Bovee (b) (4) (b) (4)	15 Apr 2021 22:07:24

**US3732304**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:26:54**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:23:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:07:03
User entered '116'	Gordon Bovee (b) (4) (b) (4)	15 Apr 2021 22:07:24

**US3732304**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:26:54**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	15 Apr 2021 22:07:24

**US3732304**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:26:54**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:23:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:07:03
User entered '17'	Gordon Bovee (b) (4) (b) (4)	15 Apr 2021 22:07:24

**US3732304**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:26:54**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	15 Apr 2021 22:07:24



US3732304

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:26:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:23:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:07:03
User entered '99'	Gordon Bovee (b) (4) (b) (4)	15 Apr 2021 22:07:24

**US3732304**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:26:54**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	15 Apr 2021 22:07:24

**US3732304**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:26:54**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:23:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:07:03
User entered '68'	Gordon Bovee (b) (4) (b) (4)	15 Apr 2021 22:07:24

**US3732304**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:26:54**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	15 Apr 2021 22:07:24

US3732304

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:26:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:23:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:07:11
User entered 'No (N)'	Gordon Bovee (b) (4) (b) (4)	15 Apr 2021 22:06:19

US3732304

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:26:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:23:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:07:11
User entered empty.	Gordon Bovee (b) (4) (b) (4)	15 Apr 2021 22:06:19

**US3732304**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:26:54**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:23:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:07:19
User entered 'Yes (Y)'	Gordon Bovee (b) (4) (b) (4)	15 Apr 2021 22:08:00

**US3732304**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:26:54**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:23:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:07:19
User entered '15 Apr 2021'	Gordon Bovee (b) (4) (b) (4)	15 Apr 2021 22:08:00



**US3732304**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:26:54**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:23:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:07:19
User entered '11:14'	Gordon Bovee (b) (4) (b) (4)	15 Apr 2021 22:08:00

**US3732304**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:26:54**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '15 Apr 2021 11:14'	System	15 Apr 2021 22:08:00

US3732304

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:26:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:23:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:07:25
User entered 'Yes (Y)'	Gordon Bovee (b) (4) (b) (4)	15 Apr 2021 22:08:08

**US3732304**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:26:54**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Apr 2021 22:08:08

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:26:54**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:54:43
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered 'Yes (Y)'	(b) (4) Amara Yilmaz (b) (4) (b) (4)	05 Feb 2021 20:31:48

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:26:54**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:54:43
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered '05 Feb 2021'	(b) (4) Amara Yilmaz (b) (4) (b) (4)	05 Feb 2021 20:31:48

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:26:54**

[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 17:42:59
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:54:43
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered 'Clinic (Clinic)'	Amara Yilmaz (b) (4)	05 Feb 2021 20:31:48

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:26:54**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered 'UNBLND_DECIDE'	System	05 Feb 2021 20:31:48



**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:26:54**

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:54:57
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered '05 Feb 2021'	Amara Yilmaz (b) (4)	05 Feb 2021 20:32:04

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:26:54**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:44:04

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:26:54**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:54:57
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered 'Yes (Y)'	(b) (4) Amara Yilmaz (b) (4) (b) (4)	05 Feb 2021 20:32:04

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:26:54**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:44:04

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:26:54**

**Date of unblinding (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:54:57
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered '05 Feb 2021'	Amara Yilmaz (b) (4)	05 Feb 2021 20:32:04

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:26:54**

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:54:57
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered 'Placebo (Placebo)'	(b) (4) Amara Yilmaz (b) (4) (b) (4)	05 Feb 2021 20:32:04

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:26:54**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:54:57
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered 'Placebo (Placebo)'	(b) (4) Amara Yilmaz (b) (4) (b) (4)	05 Feb 2021 20:32:04

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:26:54**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:54:57
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered 'Placebo (Placebo)'	(b) (4) Amara Yilmaz (b) (4) (b) (4)	05 Feb 2021 20:32:04



**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:26:54**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:54:57
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered 'Yes (Y)'	(b) (4) Amara Yilmaz (b) (4) (b) (4)	05 Feb 2021 20:32:04

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:26:54**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered '1'	System	05 Feb 2021 20:32:04

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:26:54**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered 'I'	System	05 Feb 2021 20:32:04

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:26:54**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:59:01
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered empty.	Gordon Bovee (b) (4)	06 Feb 2021 00:26:19

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:26:54**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:59:01
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered empty.	Gordon Bovee (b) (4)	06 Feb 2021 00:26:19

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:26:54**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered empty.	System	06 Feb 2021 00:26:19
DataPoint set to visible.	System	05 Feb 2021 20:32:04

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:26:54**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:59:01
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered empty.	Gordon Bovee (b) (4)	06 Feb 2021 00:26:19

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:26:54**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:59:01
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered empty.	Gordon Bovee (b) (4)	06 Feb 2021 00:26:19



**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:26:54**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered empty.	System	06 Feb 2021 00:26:19
DataPoint set to visible.	System	05 Feb 2021 20:32:04

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User accepted default value 'Pre-Dose (PREDOSE)'	Gordon Bovee (b) (4)	06 Feb 2021 00:26:19

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:59:01
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered 'Yes (Y)'	(b) (4) Gordon Bovee (b) (4) (b) (4)	06 Feb 2021 00:26:19

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:59:01
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered '05 Feb 2021'	(b) (4) Gordon Bovee (b) (4) (b) (4)	06 Feb 2021 00:26:19

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:59:01
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered '11:44'	(b) (4) Gordon Bovee (b) (4) (b) (4)	06 Feb 2021 00:26:19

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered '05 Feb 2021 11:44'	System	06 Feb 2021 00:26:19

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:59:01
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered '98.5' F	(b) (4) Gordon Bovee (b) (4) (b) (4)	06 Feb 2021 00:26:19

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:59:01
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered 'Oral (Oral)'	(b) (4) Gordon Bovee (b) (4) (b) (4)	06 Feb 2021 00:26:19



**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:26:54**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:59:01
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered empty.	(b) (4) Gordon Bovee (b) (4) (b) (4)	06 Feb 2021 00:26:19

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:59:01
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered '82'	(b) (4) Gordon Bovee (b) (4) (b) (4)	06 Feb 2021 00:26:19

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered 'bpm'	System	06 Feb 2021 00:26:19

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:59:01
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered '16'	(b) (4) Gordon Bovee (b) (4) (b) (4)	06 Feb 2021 00:26:19

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered 'breaths/min'	System	06 Feb 2021 00:26:19

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:59:01
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered '121'	(b) (4) Gordon Bovee (b) (4) (b) (4)	06 Feb 2021 00:26:19

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered 'mmHg'	System	06 Feb 2021 00:26:19

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:59:01
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered '81'	(b) (4) Gordon Bovee (b) (4) (b) (4)	06 Feb 2021 00:26:19



**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered 'mmHg'	System	06 Feb 2021 00:26:19

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:26:54**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:59:01
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered empty.	(b) (4) Gordon Bovee (b) (4) (b) (4)	06 Feb 2021 00:26:19

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:26:54**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:59:01
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered empty.	(b) (4) Gordon Bovee (b) (4) (b) (4)	06 Feb 2021 00:26:19

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:26:54**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered empty.	System	06 Feb 2021 00:26:19
DataPoint set to visible.	System	05 Feb 2021 20:32:04

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User accepted default value 'Post-Dose (POSTDOSE)'	Gordon Bovee (b) (4) (b) (4)	06 Feb 2021 00:26:19

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:59:01
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered 'Yes (Y)'	(b) (4) Gordon Bovee (b) (4) (b) (4)	06 Feb 2021 00:26:19

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:59:01
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered '05 Feb 2021'	(b) (4) Gordon Bovee (b) (4) (b) (4)	06 Feb 2021 00:26:19

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:59:01
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered '13:01'	(b) (4) Gordon Bovee (b) (4) (b) (4)	06 Feb 2021 00:26:19



**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered '05 Feb 2021 13:01'	System	06 Feb 2021 00:26:19

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:59:01
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered '99.0' F	(b) (4) Gordon Bovee (b) (4) (b) (4)	06 Feb 2021 00:26:19

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:59:01
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered 'Oral (Oral)'	(b) (4) Gordon Bovee (b) (4) (b) (4)	06 Feb 2021 00:26:19

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:26:54**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:59:01
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered empty.	(b) (4) Gordon Bovee (b) (4) (b) (4)	06 Feb 2021 00:26:19

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:59:01
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered '76'	(b) (4) Gordon Bovee (b) (4) (b) (4)	06 Feb 2021 00:26:19

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered 'bpm'	System	06 Feb 2021 00:26:19

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:59:01
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered '16'	(b) (4) Gordon Bovee (b) (4) (b) (4)	06 Feb 2021 00:26:19

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered 'breaths/min'	System	06 Feb 2021 00:26:19



**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:59:01
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered '126'	(b) (4) Gordon Bovee (b) (4) (b) (4)	06 Feb 2021 00:26:19

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered 'mmHg'	System	06 Feb 2021 00:26:19

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:59:01
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered '78'	(b) (4) Gordon Bovee (b) (4) (b) (4)	06 Feb 2021 00:26:19

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered 'mmHg'	System	06 Feb 2021 00:26:19

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:26:54**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:58:11
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered 'Yes (Y)'	(b) (4) Gordon Bovee (b) (4) (b) (4)	06 Feb 2021 00:22:55

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:26:54**

[Date of examination \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:58:11
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered '05 Feb 2021'	Gordon Bovee (b) (4)	06 Feb 2021 00:22:55

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:26:54**

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:58:30
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered 'Yes (Y)'	(b) (4) Gordon Bovee (b) (4) (b) (4)	06 Feb 2021 00:23:48

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:26:54**

[Date of test \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:58:30
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered '05 Feb 2021'	(b) (4) Gordon Bovee (b) (4) (b) (4)	06 Feb 2021 00:23:48



**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:26:54**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:58:30
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered 'Urine (URINE)'	(b) (4) Gordon Bovee (b) (4) (b) (4)	06 Feb 2021 00:23:48

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:26:54**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:58:30
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered 'Negative (NEGATIVE)'	(b) (4) Gordon Bovee (b) (4) (b) (4)	06 Feb 2021 00:23:48

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:26:54**

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:58:30
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered 'No (N)'	(b) (4) Gordon Bovee (b) (4) (b) (4)	06 Feb 2021 00:23:48

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:26:54**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:58:30
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered '05 Feb 2021'	(b) (4) Gordon Bovee (b) (4) (b) (4)	06 Feb 2021 00:23:48

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:26:54**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:58:30
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered '11:50'	(b) (4) Gordon Bovee (b) (4) (b) (4)	06 Feb 2021 00:23:48

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:26:54**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered '05 Feb 2021 11:50'	System	06 Feb 2021 00:23:48

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:26:54**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:59:22
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered 'Yes (Y)'	(b) (4) Amara Yilmaz (b) (4) (b) (4)	05 Feb 2021 20:32:21

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:26:54**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:59:22
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered empty.	(b) (4) Amara Yilmaz (b) (4) (b) (4)	05 Feb 2021 20:32:21



US3732304

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:26:54

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:59:22
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered empty.	(b) (4) Amara Yilmaz (b) (4) (b) (4)	05 Feb 2021 20:32:21

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:26:54**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered 'mRNA-1273'	System	05 Feb 2021 20:32:21
DataPoint set to visible.	System	05 Feb 2021 20:32:04

US3732304

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:26:54

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:59:22
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered '05 Feb 2021'	Amara Yilmaz (b) (4)	05 Feb 2021 20:32:21

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:26:54**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:59:22
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered '12:28'	(b) (4) Amara Yilmaz (b) (4) (b) (4)	05 Feb 2021 20:32:21

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:26:54**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered '05 Feb 2021 12:28'	System	05 Feb 2021 20:32:21

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:26:54**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:59:22
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered 'Left Arm (LEFT ARM)'	(b) (4) Amara Yilmaz (b) (4) (b) (4)	05 Feb 2021 20:32:21

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:26:54**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:59:22
User entered 'ONCE'	System	05 Feb 2021 20:32:21

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:26:54**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered 'INTRAMUSCULAR'	System	05 Feb 2021 20:32:21



**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:26:54**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:55:04
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered 'Yes (Y)'	(b) (4) Gordon Bovee (b) (4) (b) (4)	06 Feb 2021 00:20:51

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:26:54**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:55:04
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered '05 Feb 2021'	(b) (4) Gordon Bovee (b) (4) (b) (4)	06 Feb 2021 00:20:51

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:26:54**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:55:04
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered '11:00'	(b) (4) Gordon Bovee (b) (4) (b) (4)	06 Feb 2021 00:20:51

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:26:54**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered '05 Feb 2021 11:00'	System	06 Feb 2021 00:20:51

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:26:54**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:55:09
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered 'Yes (Y)'	(b) (4) Gordon Bovee (b) (4) (b) (4)	06 Feb 2021 00:21:07

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:26:54**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:55:09
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered '05 Feb 2021'	(b) (4) Gordon Bovee (b) (4) (b) (4)	06 Feb 2021 00:21:07

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:26:54**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:55:09
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered '11:09'	(b) (4) Gordon Bovee (b) (4) (b) (4)	06 Feb 2021 00:21:07

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:26:54**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered '05 Feb 2021 11:09'	System	06 Feb 2021 00:21:07



**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:26:54**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:59:37
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	06 Feb 2021 00:27:22

**US3732304**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:26:54**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:42:59
User entered 'I'	System	06 Feb 2021 00:27:22

**US3732304**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:26:54**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:35:19
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:59:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered 'Yes (Y)'	(b) (4) Linda Vega (b) (4) (b) (4)	12 Feb 2021 18:09:51

**US3732304**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:26:54**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:35:19
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:59:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered '12 Feb 2021'	(b) (4) Linda Vega (b) (4) (b) (4)	12 Feb 2021 18:09:51

**US3732304**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:26:54**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:35:19
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:59:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Linda Vega (b) (4) (b) (4)	12 Feb 2021 18:09:51

**US3732304**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:26:54**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:35:19
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:59:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered empty.	Linda Vega (b) (4)	12 Feb 2021 18:09:51

**US3732304**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:26:54**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:35:19
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 21:00:12
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered 'Yes (Y)'	Linda Vega (b) (4)	12 Feb 2021 18:09:55

**US3732304**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:26:54**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:35:19
User entered 'I'	System	12 Feb 2021 18:09:55



**US3732304**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:26:54**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:35:19
User entered '1'	System	12 Feb 2021 18:09:55
DataPoint set to visible.	System	12 Feb 2021 18:09:55

**US3732304**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:26:54**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:34:01
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 21:00:53
User entered 'Yes (Y)'	Gordon Bovee (b) (4) (b) (4)	05 Mar 2021 21:39:59

**US3732304**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:26:54**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:34:01
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 21:00:53
User entered '05 Mar 2021'	Gordon Bovee (b) (4) (b) (4)	05 Mar 2021 21:39:59

**US3732304**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:26:54**

[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 00:34:01
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 21:00:53
User entered 'Clinic (Clinic)'	Gordon Bovee (b) (4) (b) (4)	05 Mar 2021 21:39:59

**US3732304**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:26:54**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:34:01
User entered 'OLD29'	System	05 Mar 2021 21:39:59

**US3732304**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:34:01
User accepted default value 'Pre-Dose (PREDOSE)'	Gordon Bovee (b) (4) (b) (4)	05 Mar 2021 23:09:08

**US3732304**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:34:01
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 21:02:24
User entered 'Yes (Y)'	Gordon Bovee (b) (4) (b) (4)	05 Mar 2021 23:09:08

**US3732304**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:34:01
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 21:02:24
User entered '05 Mar 2021'	Gordon Bovee (b) (4) (b) (4)	05 Mar 2021 23:09:08



**US3732304**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:26:54**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:34:01
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 21:02:24
User entered '12:43'	Gordon Bovee (b) (4) (b) (4)	05 Mar 2021 23:09:08

**US3732304**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:34:01
User entered '05 Mar 2021 12:43'	System	05 Mar 2021 23:09:08

**US3732304**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:34:01
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 21:02:24
User entered '97.8' F	Gordon Bovee (b) (4) (b) (4)	05 Mar 2021 23:09:08

**US3732304**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:34:01
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 21:02:24
User entered 'Oral (Oral)'	Gordon Bovee (b) (4) (b) (4)	05 Mar 2021 23:09:08

**US3732304**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:26:54**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:34:01
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 21:02:24
User entered empty.	Gordon Bovee (b) (4) (b) (4)	05 Mar 2021 23:09:08

**US3732304**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:34:01
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 21:02:24
User entered '89'	Gordon Bovee (b) (4) (b) (4)	05 Mar 2021 23:09:08

**US3732304**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:34:01
User entered 'bpm'	System	05 Mar 2021 23:09:08

**US3732304**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:34:01
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 21:02:24
User entered '16'	Gordon Bovee (b) (4) (b) (4)	05 Mar 2021 23:09:08



**US3732304**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:34:01
User entered 'breaths/min'	System	05 Mar 2021 23:09:08

**US3732304**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:34:01
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 21:02:24
User entered '119'	Gordon Bovee (b) (4) (b) (4)	05 Mar 2021 23:09:08

**US3732304**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:34:01
User entered 'mmHg'	System	05 Mar 2021 23:09:08

**US3732304**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:34:01
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 21:02:24
User entered '85'	Gordon Bovee (b) (4) (b) (4)	05 Mar 2021 23:09:08

**US3732304**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:34:01
User entered 'mmHg'	System	05 Mar 2021 23:09:08

**US3732304**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:34:01
User accepted default value 'Post-Dose (POSTDOSE)'	Gordon Bovee (b) (4) (b) (4)	05 Mar 2021 23:09:08

**US3732304**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:34:01
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 21:02:24
User entered 'Yes (Y)'	Gordon Bovee (b) (4) (b) (4)	05 Mar 2021 23:09:08

**US3732304**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:26:54**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:34:01
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 21:02:24
User entered '05 Mar 2021'	Gordon Bovee (b) (4) (b) (4)	05 Mar 2021 23:09:08



**US3732304**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:34:01
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 21:02:24
User entered '14:09'	Gordon Bovee (b) (4) (b) (4)	05 Mar 2021 23:09:08

**US3732304**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:34:01
User entered '05 Mar 2021 14:09'	System	05 Mar 2021 23:09:08

**US3732304**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:34:01
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 21:02:24
User entered '98.2' F	Gordon Bovee (b) (4) (b) (4)	05 Mar 2021 23:09:08

**US3732304**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:34:01
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 21:02:24
User entered 'Oral (Oral)'	Gordon Bovee (b) (4) (b) (4)	05 Mar 2021 23:09:08

**US3732304**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:26:54**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:34:01
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 21:02:24
User entered empty.	Gordon Bovee (b) (4) (b) (4)	05 Mar 2021 23:09:08

**US3732304**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:34:01
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 21:02:24
User entered '82'	Gordon Bovee (b) (4) (b) (4)	05 Mar 2021 23:09:08

**US3732304**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:34:01
User entered 'bpm'	System	05 Mar 2021 23:09:08

**US3732304**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:34:01
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 21:02:24
User entered '16'	Gordon Bovee (b) (4) (b) (4)	05 Mar 2021 23:09:08



**US3732304**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:34:01
User entered 'breaths/min'	System	05 Mar 2021 23:09:08

**US3732304**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:34:01
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 21:02:24
User entered '118'	Gordon Bovee (b) (4) (b) (4)	05 Mar 2021 23:09:08

**US3732304**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:34:01
User entered 'mmHg'	System	05 Mar 2021 23:09:08

**US3732304**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:34:01
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 21:02:24
User entered '77'	Gordon Bovee (b) (4) (b) (4)	05 Mar 2021 23:09:08

**US3732304**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:34:01
User entered 'mmHg'	System	05 Mar 2021 23:09:08

**US3732304**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:26:54**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:34:01
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 21:01:13
User entered 'Yes (Y)'	Gordon Bovee (b) (4) (b) (4)	05 Mar 2021 23:03:41

**US3732304**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:26:54**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:34:01
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 21:01:13
User entered '05 Mar 2021'	Gordon Bovee (b) (4) (b) (4)	05 Mar 2021 23:03:41

**US3732304**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:26:54**

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:34:01
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 21:01:37
User entered 'Yes (Y)'	Gordon Bovee (b) (4) (b) (4)	05 Mar 2021 23:07:06



**US3732304**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:26:54**

**Date of test (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:34:01
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 21:01:37
User entered '05 Mar 2021'	Gordon Bovee (b) (4) (b) (4)	05 Mar 2021 23:07:06

**US3732304**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:26:54**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:34:01
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 21:01:37
User entered 'Urine (URINE)'	Gordon Bovee (b) (4) (b) (4)	05 Mar 2021 23:07:06

**US3732304**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:26:54**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:34:01
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 21:01:37
User entered 'Negative (NEGATIVE)'	Gordon Bovee (b) (4) (b) (4)	05 Mar 2021 23:07:06

**US3732304**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:26:54**

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:34:01
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 21:01:37
User entered 'No (N)'	Gordon Bovee (b) (4) (b) (4)	05 Mar 2021 23:07:06

**US3732304**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:26:54**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:34:01
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 21:01:37
User entered empty.	Gordon Bovee (b) (4) (b) (4)	05 Mar 2021 23:07:06

**US3732304**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:26:54**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:34:01
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 21:01:37
User entered empty.	Gordon Bovee (b) (4) (b) (4)	05 Mar 2021 23:07:06

**US3732304**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:26:54**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:34:01
User entered empty.	System	05 Mar 2021 23:07:06

**US3732304**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:26:54**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:34:01
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 21:02:39
User entered 'Yes (Y)'	Gordon Bovee (b) (4) (b) (4)	05 Mar 2021 21:40:35



**US3732304**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:26:54**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:34:01
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 21:02:39
User entered empty.	Gordon Bovee (b) (4) (b) (4)	05 Mar 2021 21:40:35

US3732304

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:26:54

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 00:34:01
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 21:02:39
User entered empty.	Gordon Bovee (b) (4)	05 Mar 2021 21:40:35

**US3732304**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:26:54**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:34:01
User entered 'mRNA-1273'	System	05 Mar 2021 21:40:35
DataPoint set to visible.	System	12 Feb 2021 18:09:55

**US3732304**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:26:54**

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:34:01
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 21:02:39
User entered '05 Mar 2021'	Gordon Bovee (b) (4) (b) (4)	05 Mar 2021 21:40:35

**US3732304**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:26:54**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:34:01
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 21:02:39
User entered '13:35'	Gordon Bovee (b) (4) (b) (4)	05 Mar 2021 21:40:35

**US3732304**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:26:54**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:34:01
User entered '05 Mar 2021 13:35'	System	05 Mar 2021 21:40:35

**US3732304**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:26:54**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:34:01
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 21:02:39
User entered 'Left Arm (LEFT ARM)'	Gordon Bovee (b) (4) (b) (4)	05 Mar 2021 21:40:35

**US3732304**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:26:54**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:34:01
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 21:02:39
User entered 'ONCE'	System	05 Mar 2021 21:40:35



**US3732304**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:26:54**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:34:01
User entered 'INTRAMUSCULAR'	System	05 Mar 2021 21:40:35

**US3732304**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:26:54**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:34:01
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 21:02:58
User entered 'Yes (Y)'	Gordon Bovee (b) (4) (b) (4)	05 Mar 2021 23:09:36

**US3732304**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:26:54**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 00:34:01
User entered 'I'	System	05 Mar 2021 23:09:36

**US3732304**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:26:54**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:43
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:38:32
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
User entered 'Yes (Y)'	Linda Vega (b) (4)	12 Mar 2021 19:39:22

**US3732304**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:26:54**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:43
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:38:32
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
User entered '12 Mar 2021'	(b) (4) Linda Vega (b) (4) (b) (4)	12 Mar 2021 19:39:22

**US3732304**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:26:54**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:43
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:38:32
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Linda Vega (b) (4) (b) (4)	12 Mar 2021 19:39:22

**US3732304**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:26:54**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:43
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:38:32
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
User entered empty.	Linda Vega (b) (4)	12 Mar 2021 19:39:22

**US3732304**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:26:54**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:43
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:38:54
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
User entered 'Yes (Y)'	Linda Vega (b) (4)	12 Mar 2021 19:39:28



**US3732304**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:26:54**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:01:43
User entered 'I'	System	12 Mar 2021 19:39:28

**US3732304**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:26:54**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:23:32
	(b) (4)	
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	15 Apr 2021 22:14:42
	(b) (4)	

**US3732304**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:26:54**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:23:32
	(b) (4)	
User entered '15 Apr 2021'	Gordon Bovee (b) (4)	15 Apr 2021 22:14:42
	(b) (4)	

**US3732304**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:26:54**

[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 22:23:32
	(b) (4)	
User entered 'Clinic (Clinic)'	Gordon Bovee (b) (4)	15 Apr 2021 22:14:42
	(b) (4)	

**US3732304**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:26:54**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	15 Apr 2021 22:14:42

**US3732304**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:26:54**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:23:32
	(b) (4)	
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	15 Apr 2021 22:21:31
	(b) (4)	

**US3732304**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:26:54**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:23:32
	(b) (4)	
User entered '15 Apr 2021'	Gordon Bovee (b) (4)	15 Apr 2021 22:21:31
	(b) (4)	

**US3732304**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:26:54**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:23:32
	(b) (4)	
User entered '11:02'	Gordon Bovee (b) (4)	15 Apr 2021 22:21:31
	(b) (4)	



**US3732304**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:26:54**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '15 Apr 2021 11:02'	System	15 Apr 2021 22:21:31

**US3732304**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:26:54**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:23:32
	(b) (4)	
User entered '98.8' F	Gordon Bovee (b) (4)	15 Apr 2021 22:21:31
	(b) (4)	

**US3732304**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:26:54**

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:23:32
	(b) (4)	
User entered 'Oral (Oral)'	Gordon Bovee (b) (4)	15 Apr 2021 22:21:31
	(b) (4)	

**US3732304**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:26:54**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:23:32
	(b) (4)	
User entered empty.	Gordon Bovee (b) (4)	15 Apr 2021 22:21:31
	(b) (4)	

**US3732304**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:26:54**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:23:32
	(b) (4)	
User entered '116'	Gordon Bovee (b) (4)	15 Apr 2021 22:21:31
	(b) (4)	

**US3732304**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:26:54**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	15 Apr 2021 22:21:31

**US3732304**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:26:54**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:23:32
	(b) (4)	
User entered '17'	Gordon Bovee (b) (4)	15 Apr 2021 22:21:31
	(b) (4)	

**US3732304**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:26:54**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	15 Apr 2021 22:21:31



**US3732304**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:26:54**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:23:32
User entered '99'	(b) (4) Gordon Bovee (b) (4)	15 Apr 2021 22:21:31
	(b) (4)	

**US3732304**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:26:54**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	15 Apr 2021 22:21:31

**US3732304**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:26:54**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:23:32
	(b) (4)	
User entered '68'	Gordon Bovee (b) (4)	15 Apr 2021 22:21:31
	(b) (4)	

**US3732304**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:26:54**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	15 Apr 2021 22:21:31

**US3732304**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:26:54**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:23:32
	(b) (4)	
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	15 Apr 2021 22:20:16
	(b) (4)	

**US3732304**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:26:54**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:23:32
	(b) (4)	
User entered '15 Apr 2021'	Gordon Bovee (b) (4)	15 Apr 2021 22:20:16
	(b) (4)	

**US3732304**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:26:54**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:23:03
	(b) (4)	
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	15 Apr 2021 22:22:09
	(b) (4)	

**US3732304**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:26:54**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:23:03
	(b) (4)	
User entered '15 Apr 2021'	Gordon Bovee (b) (4)	15 Apr 2021 22:22:09
	(b) (4)	



**US3732304**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:26:54**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:23:03
	(b) (4)	
User entered '11:14'	Gordon Bovee (b) (4)	15 Apr 2021 22:22:09
	(b) (4)	

**US3732304**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:26:54**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '15 Apr 2021 11:14'	System	15 Apr 2021 22:22:09

**US3732304**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 10 Jun 2021 09:26:54**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:32:03
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:16:33
User entered 'Yes (Y)'	Amara Yilmaz (b) (4) (b) (4)	19 Oct 2020 16:49:35

**US3732304**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:26:54**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:13

US3732304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:26:54

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:13
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:19:52
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site pain, LLT: Pain injection site - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 16:52:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 16:52:21
Data point term sent to Coder	System	19 Oct 2020 16:50:59
User entered 'pain at injection site'	Amara Yilmaz (b) (4) (b) (4)	19 Oct 2020 16:50:26

**US3732304**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:13
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:19:52
User entered 'No (N)'	Amara Yilmaz (b) (4) (b) (4)	19 Oct 2020 16:50:26

US3732304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:26:54

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:13
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 21:04:05
User closed query 'Per DM CLR: Note, this is a solicited event per protocol. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or provide clarification.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 05:26:29
Query 'Per DM CLR: Note, this is a solicited event per protocol. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or provide clarification.' answered with 'updated ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 22:25:27
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 22:23:16
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 22:23:16
User opened query 'Per DM CLR: Note, this is a solicited event per protocol. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or provide clarification.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 06:00:49
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:19:52
User entered 'No (N)'	Amara Yilmaz (b) (4)	19 Oct 2020 16:50:26

**US3732304**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:13
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:19:52
User entered 'No (N)'	Amara Yilmaz (b) (4)	19 Oct 2020 16:50:26
	(b) (4)	



US3732304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:26:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:13
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 21:04:16
User closed query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom PAIN AT INJECTION SITE on 08 OCT 2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM).		25 Nov 2020 05:26:39
Query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom PAIN AT INJECTION SITE on 08 OCT 2020. Please review if this should be reconciled. Else, provide clarification on dates.' answered with 'updated per eDiary start date' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 22:25:36
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 22:24:33
User entered '08 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 22:24:33
User opened query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom PAIN AT INJECTION SITE on 08 OCT 2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 06:01:15
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:19:52
User entered '10 Oct 2020'	Amara Yilmaz (b) (4) (b) (4)	19 Oct 2020 16:50:26

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:26:54

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:13
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 21:04:21
User closed query 'Data is required. Please provide.' (Site from System).		27 Nov 2020 19:17:37
Query 'Data is required. Please provide.' answered with 'time is unknown' (Site from System).		24 Nov 2020 22:25:45
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Nov 2020 22:25:17
User closed query 'Data entered is non-conformant.' Please correct.' (Site from System).	System	24 Nov 2020 22:25:17
User entered empty; reason for change Per Query Resolution	(b) (4), (b) (6)	24 Nov 2020 22:25:17
User opened query 'Data entered is non-conformant.' Please correct.' (Site from System).	System	24 Nov 2020 22:25:06
User closed query 'Data is required. Please provide.' (Site from System).	System	24 Nov 2020 22:25:06
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 22:25:06
User entered 'un:un' (non-conformant).	(b) (4), (b) (6)	24 Nov 2020 22:25:06
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Nov 2020 22:24:33
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:19:52
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	22 Oct 2020 21:49:41
User entered empty; reason for change Per Query Resolution	(b) (4), (b) (6)	22 Oct 2020 21:49:41
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	22 Oct 2020 21:49:08
User entered '19:32' reason for change: New Information	(b) (4), (b) (6)	22 Oct 2020 21:49:08
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	19 Oct 2020 16:50:26

**US3732304**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:26:54**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:13
User entered empty.	System	24 Nov 2020 22:25:17
User entered '08 Oct 2020 UN:UN' (non-conformant).	System	24 Nov 2020 22:25:06
User entered empty.	System	22 Oct 2020 21:49:41
User entered '10 Oct 2020 19:32'	System	22 Oct 2020 21:49:08
User entered empty.	System	19 Oct 2020 16:50:26

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:13
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:19:52
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	22 Oct 2020 21:49:08
User entered 'Yes (Y)'	Amara Yilmaz (b) (4)	19 Oct 2020 16:50:26
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:26:54**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:13
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:19:52
User entered '18 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Oct 2020 21:49:08
User entered empty.	Amara Yilmaz (b) (4)	19 Oct 2020 16:50:26
	(b) (4)	

**US3732304**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:26:54**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:13
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	27 Nov 2020 19:17:39
Query 'Data is required. Please provide.' answered with 'time is unknown' (Site from System).	(b) (4), (b) (6)	24 Nov 2020 22:25:51
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Nov 2020 22:24:33
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:19:52
User entered empty.	Amara Yilmaz (b) (4)	19 Oct 2020 16:50:26
	(b) (4)	

**US3732304**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:26:54**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:13
User entered empty.	System	19 Oct 2020 16:50:26

**US3732304**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:13
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:19:52
User entered 'Grade 1/Mild (Grade 1/Mild)'	Amara Yilmaz (b) (4) (b) (4)	19 Oct 2020 16:50:26



**US3732304**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:13
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:19:52
User entered 'No (N)'	Amara Yilmaz (b) (4)	19 Oct 2020 16:50:26
	(b) (4)	

**US3732304**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:13
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:19:52
User entered '0'	Amara Yilmaz (b) (4)	19 Oct 2020 16:50:26
	(b) (4)	

**US3732304**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:13
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:19:52
User entered '0'	Amara Yilmaz (b) (4) (b) (4)	19 Oct 2020 16:50:26

**US3732304**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:13
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:19:52
User entered '0'	Amara Yilmaz (b) (4)	19 Oct 2020 16:50:26
	(b) (4)	

**US3732304**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:26:54**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:13
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:19:52
User entered empty.	Amara Yilmaz (b) (4)	19 Oct 2020 16:50:26
	(b) (4)	

**US3732304**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:13
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:19:52
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	19 Oct 2020 16:50:26

**US3732304**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:13
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:19:52
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	19 Oct 2020 16:50:26

**US3732304**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:13
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:19:52
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	19 Oct 2020 16:50:26



**US3732304**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:13
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:19:52
User entered '0'	Amara Yilmaz (b) (4)	19 Oct 2020 16:50:26
	(b) (4)	

**US3732304**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:13
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:19:52
User entered '0'	Amara Yilmaz (b) (4) (b) (4)	19 Oct 2020 16:50:26

**US3732304**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:13
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:19:52
User entered '0'	Amara Yilmaz (b) (4) (b) (4)	19 Oct 2020 16:50:26

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:13
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:19:52
User entered 'Related (RELATED)'	Amara Yilmaz (b) (4)	19 Oct 2020 16:50:26
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:13
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:19:52
User entered 'Related (RELATED)'	Amara Yilmaz (b) (4)	19 Oct 2020 16:50:26
	(b) (4)	

**US3732304**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:13
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:19:52
User entered 'None (NONE)'	Amara Yilmaz (b) (4)	19 Oct 2020 16:50:26
	(b) (4)	

**US3732304**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:26:54**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:13
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:19:52
User entered 'l'	Amara Yilmaz (b) (4) (b) (4)	19 Oct 2020 16:50:26

**US3732304**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:13
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:19:52
User entered '0'	Amara Yilmaz (b) (4)	19 Oct 2020 16:50:26
	(b) (4)	



**US3732304**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:13
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:19:52
User entered '0'	Amara Yilmaz (b) (4)	19 Oct 2020 16:50:26
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:13
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:19:52
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4), (b) (6)	22 Oct 2020 21:49:08
New Information		
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Amara Yilmaz (b) (4)	19 Oct 2020 16:50:26
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:26:54**

[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 10:16:13
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:19:52
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	19 Oct 2020 16:50:26

**US3732304**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:13
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:19:52
User entered empty.	Amara Yilmaz (b) (4)	19 Oct 2020 16:50:26
	(b) (4)	

**US3732304**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:13
User entered '0'	System	19 Oct 2020 16:50:26

**US3732304**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:13
User entered '0'	System	19 Oct 2020 16:50:26

**US3732304**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:16:13

**US3732304**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:26:54**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:16:44
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:22
User entered		
'USA-US102-2020-mRNA-1273-P301000004'	System	04 Nov 2020 16:37:53
User entered 'New'	(b) (4), (b) (6)	04 Nov 2020 16:37:53



**US3732304**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 06:25:15
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection' answered with 'Per MR, covid PCR test negative' (Site from DM).	He (Helen) Pu (b) (4)	09 Apr 2021 18:08:35
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 19:26:27
Query 'US3732304' canceled (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 13:00:11
User opened query 'US3732304' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 13:00:09
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:16:46
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Pulmonary vascular disorders, HLT: Pulmonary thrombotic and embolic conditions, PT: Pulmonary embolism, LLT: Pulmonary embolism - version MedDRA\\23.0.	Coder Import (b) (4)	03 Nov 2020 20:28:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Nov 2020 20:28:42
Data point term sent to Coder	System	03 Nov 2020 20:28:05
User entered 'bilateral pulmonary embolism'	(b) (4), (b) (6)	03 Nov 2020 20:27:56

**US3732304**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:16:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Nov 2020 20:27:56

**US3732304**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:16:53
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 20:27:56

**US3732304**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:16:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Nov 2020 20:27:56

US3732304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:26:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:23:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:10:42
User closed query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms (Per medical records, the subject started having symptoms 4 days prior to hospital admission). ' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 17:33:18
Query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms (Per medical records, the subject started having symptoms 4 days prior to hospital admission). ' answered with 'Updated per medical records to reflect same start date of symptom onset.' (Site from Safety).	(b) (4), (b) (6)	20 Apr 2021 19:49:53
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 19:49:26
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 19:49:26
User entered '25 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 19:49:26
User opened query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms (Per medical records, the subject started having symptoms 4 days prior to hospital admission). ' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 14:11:05
Query '1. PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms (Per medical records, the subject started having symptoms 4 days prior to hospital admission). ' canceled (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 14:10:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:26:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query '1. PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms (Per medical records, the subject started having symptoms 4 days prior to hospital admission). ' (Site from Safety). User signature succeeded.	(b) (4), (b) (6)	19 Apr 2021 14:10:52
	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:19:36
User entered '29 Oct 2020'	(b) (4), (b) (6)	03 Nov 2020 20:27:56

**US3732304**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:16:57
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 20:27:56

**US3732304**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:26:54**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Nov 2020 20:27:56



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:26:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:23:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 18:10:48
DataPoint Un-verified.	Gordon Bovee (b) (4)	15 Apr 2021 22:25:58
	(b) (4)	
Signature has been broken.	Gordon Bovee (b) (4)	15 Apr 2021 22:25:58
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Gordon Bovee (b) (4)	15 Apr 2021 22:25:58
	(b) (4)	
User closed query 'Per MM, please provide the end date.' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 06:25:22
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
	(b) (4)	
Query 'Per MM, please provide the end date.' answered with 'symptoms still ongoing' (Site from DM).	He (Helen) Pu (b) (4)	09 Apr 2021 18:05:12
	(b) (4)	
User opened query 'Per MM, please provide the end date.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 19:26:18
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:16:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Nov 2020 20:27:56

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:26:54

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:23:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:10:50
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	15 Apr 2021 22:25:58
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	15 Apr 2021 22:25:58
DataPoint Un-verified.	Gordon Bovee (b) (4)	15 Apr 2021 22:25:58
Signature has been broken.	(b) (4) Gordon Bovee (b) (4)	15 Apr 2021 22:25:58
User entered '15 Apr 2021' reason for change: New Information	(b) (4) Gordon Bovee (b) (4)	15 Apr 2021 22:25:58
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	15 Apr 2021 22:25:06
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 13:27:29
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
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 'symptoms still ongoing' (Site from Safety).	(b) (4) He (Helen) Pu (b) (4)	09 Apr 2021 18:05:22
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)	04 Feb 2021 18:55:42
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 this AE has resolved and if an End date should be recorded. If yes, please update applicable details as appropriate. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 14:50:45

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:26:54

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details as appropriate. Otherwise, comment to confirm that this AE is still ongoing.' answered with 'AE is ongoing ' (Site from DM).	Amara Yilmaz (b) (4)	26 Jan 2021 19:33:37
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 this AE has resolved and if an End date should be recorded. If yes, please update applicable details as appropriate. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 23:15:39
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)	25 Nov 2020 20:02:31
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 review' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 22:42:00
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)	13 Nov 2020 16:25:40
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:17:01
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 20:27:56

**US3732304**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:26:54**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:17:04
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 20:27:56

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:26:54**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' canceled (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 16:40:14
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)	04 Dec 2020 13:01:10
User entered empty.	System	03 Nov 2020 20:27:56

**US3732304**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:17:06
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	03 Nov 2020 20:27:56

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:26:54

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:17:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Nov 2020 20:27:56

**US3732304**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:17:11
User entered '0'	(b) (4), (b) (6)	03 Nov 2020 20:27:56



**US3732304**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:17:13
User entered '0'	(b) (4), (b) (6)	03 Nov 2020 20:27:56

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:26:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'Per CDM Re-query: Response is noted, kindly complete Hospital Discharge Date, or Admitted to ICU fields once data are available. Keep query open until updates have been made.' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 06:25:27
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
Query 'Per CDM Re-query: Response is noted, kindly complete Hospital Discharge Date, or Admitted to ICU fields once data are available. Keep query open until updates have been made.' answered with 'updated' (Site from DM).	He (Helen) Pu (b) (4)	09 Apr 2021 18:29:19
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).		09 Apr 2021 18:29:07
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 by data change (Site from System).		09 Apr 2021 18:29:07
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	16 Feb 2021 20:21:51
User opened query 'Per CDM Re-query: Response is noted, kindly complete Hospital Discharge Date, or Admitted to ICU fields once data are available. Keep query open until updates have been made.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 05:56:11
User closed query 'per CDM RQ: please respond to this query when data is entered' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 05:44:14
Query 'per CDM RQ: please respond to this query when data is entered' answered with 'pending medical records review' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 22:42:48

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:26:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
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)	19 Nov 2020 16:58:58
User opened query 'per CDM RQ: please respond to this query when data is entered' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 16:58:56
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:17:15
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 'Awaiting patient's medical records; will complete once records are received.' (Site from System).	(b) (4), (b) (6)	03 Nov 2020 20:33:35
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	03 Nov 2020 20:27:56
User entered 'I'	(b) (4), (b) (6)	03 Nov 2020 20:27:56

**US3732304**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:26:54**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:17:18
User entered '29 Oct 2020'	(b) (4), (b) (6)	03 Nov 2020 20:27:56

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:26:54

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety). User signature succeeded.	(b) (4), (b) (6)	12 Apr 2021 13:27:34
	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Records just sent, thank you!' (Site from Safety). DataPoint Verified.	He (Helen) Pu (b) (4)	09 Apr 2021 18:49:10
	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 21:06:26
DataPoint Un-verified.	Gordon Bovee (b) (4)	16 Feb 2021 20:21:51
	(b) (4)	
User entered '05 Nov 2020' reason for change: New Information	Gordon Bovee (b) (4)	16 Feb 2021 20:21:51
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 18:56:28
	(b) (4), (b) (6)	06 Nov 2020 22:17:21
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 20:27:56

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Folder: Adverse Events

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:24:16
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Un-verified.	He (Helen) Pu (b) (4)	09 Apr 2021 18:29:07
User entered 'No (N)' reason for change: New Information	He (Helen) Pu (b) (4)	09 Apr 2021 18:29:07
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:17:22
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 20:27:56

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:17:25
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 20:27:56

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:17:27
User entered '0'	(b) (4), (b) (6)	03 Nov 2020 20:27:56



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:17:29
User entered '0'	(b) (4), (b) (6)	03 Nov 2020 20:27:56

**US3732304**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:17:31
User entered '0'	(b) (4), (b) (6)	03 Nov 2020 20:27:56

**US3732304**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:17:38
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	03 Nov 2020 20:27:56

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:17:40
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	03 Nov 2020 20:27:56

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:26:54

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:23:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Apr 2021 21:30:54
User closed query 'PV Query: As the last dose of study drug was given on 07 Oct 2020, please update the action taken with study drug from withdrawal to not applicable.' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 16:49:17
Query 'PV Query: As the last dose of study drug was given on 07 Oct 2020, please update the action taken with study drug from withdrawal to not applicable.' answered with 'updated' (Site from Safety).	Gordon Bovee (b) (4)	23 Apr 2021 18:19:25
DataPoint Un-verified.	(b) (4)	
	Gordon Bovee (b) (4)	23 Apr 2021 18:19:07
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Per Query Resolution	(b) (4)	
	Gordon Bovee (b) (4)	23 Apr 2021 18:19:07
User opened query 'PV Query: As the last dose of study drug was given on 07 Oct 2020, please update the action taken with study drug from withdrawal to not applicable.' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 15:25:43
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:11:08
DataPoint Un-verified.	(b) (4)	
	Gordon Bovee (b) (4)	15 Apr 2021 22:25:06
Signature has been broken.	(b) (4)	
	Gordon Bovee (b) (4)	15 Apr 2021 22:25:06
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: New Information	(b) (4)	
	Gordon Bovee (b) (4)	15 Apr 2021 22:25:06
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Dec 2020 23:35:24
User closed query 'PV Query: As the last dose of study drug was given on 07 Oct 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 20:02:02
Query 'PV Query: As the last dose of study drug was given on 07 Oct 2020, please update the action taken with study drug from none to not applicable.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 22:44:32
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 22:43:57

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Folder: Adverse Events

Form: Adverse Events (2)

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Action taken with investigational product

Audit	User	Time (GMT)
User entered 'None (NONE)' reason for change:	(b) (4), (b) (6)	24 Nov 2020 22:43:34
Data Entry Error		
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 22:27:29
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	24 Nov 2020 22:27:29
reason for change: Data Entry Error		
User opened query 'PV Query: As the last dose of	(b) (4), (b) (6)	13 Nov 2020 16:24:29
study drug was given on 07 Oct 2020, please update		
the action taken with study drug from none to not		
applicable.' (Site from Safety).		
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:17:42
User entered 'None (NONE)'	(b) (4), (b) (6)	03 Nov 2020 20:27:56

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:17:45
User entered '0'	(b) (4), (b) (6)	03 Nov 2020 20:27:56

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:17:46
User entered 'I'	(b) (4), (b) (6)	03 Nov 2020 20:27:56



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:17:48
User entered '0'	(b) (4), (b) (6)	03 Nov 2020 20:27:56

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Folder: Adverse Events

Form: Adverse Events (2)

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:23:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:12:12
DataPoint Un-verified.	Gordon Bovee (b) (4)	15 Apr 2021 22:25:06
Signature has been broken.	(b) (4) Gordon Bovee (b) (4)	15 Apr 2021 22:25:06
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: New Information	Gordon Bovee (b) (4)	15 Apr 2021 22:25:06
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 13:27:57
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'AE is still open - closing query for database lock' (Site from Safety).	(b) (4) He (Helen) Pu (b) (4)	09 Apr 2021 18:29:37
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 18:55:17
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	27 Jan 2021 15:57:04
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'AE is ongoing, and patient will be seeing pulmonologist soon ' (Site from Safety).	Amara Yilmaz (b) (4)	26 Jan 2021 19:33:24

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Form: Adverse Events (2)

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[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 13:02:10
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 20:02:22
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'pending medical records review' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 22:44:41
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 16:25:20
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:17:54
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	03 Nov 2020 20:27:56

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:23:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:11:30
User closed query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	15 Apr 2021 22:35:09
DataPoint Un-verified.	Gordon Bovee (b) (4)	15 Apr 2021 22:35:09
Signature has been broken.	(b) (4) Gordon Bovee (b) (4)	15 Apr 2021 22:35:09
User entered 'shortness of breath or exertion when bending down' reason for change: Per Query Resolution	(b) (4) Gordon Bovee (b) (4)	15 Apr 2021 22:35:09
User opened query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	15 Apr 2021 22:25:06
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:18:00
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 20:27:56

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Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Per medical records, subject was diagnosed with right sided heart failure and E.coli bacteruria. Please consider adding these as separate AEs. Please leave query open until events have been added to EDC or confirmed that they will not be added. ' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 21:38:14
Query 'PV Query: Per medical records, subject was diagnosed with right sided heart failure and E.coli bacteruria. Please consider adding these as separate AEs. Please leave query open until events have been added to EDC or confirmed that they will not be added. Please leave query open until information is received. ' canceled (Site from Safety).	(b) (4), (b) (6)	03 May 2021 21:37:55
User opened query 'PV Query: Per medical records, subject was diagnosed with right sided heart failure and E.coli bacteruria. Please consider adding these as separate AEs. Please leave query open until events have been added to EDC or confirmed that they will not be added. Please leave query open until information is received. ' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 21:37:39
User closed query 'PV Query: Per medical records, subject was diagnosed with right sided heart failure and E.coli bacteruria. Please consider adding these as separate AEs ' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 21:37:33
Query 'PV Query: Per medical records, subject was diagnosed with right sided heart failure and E.coli bacteruria. Please consider adding these as separate AEs ' answered with 'Pending medical records for more information. Will add when received.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 23:32:40
User opened query 'PV Query: Per medical records, subject was diagnosed with right sided heart failure and E.coli bacteruria. Please consider adding these as separate AEs ' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 20:48:05
User closed query 'PV Query: Per medical records, subject was diagnosed with right sided heart failure and E.coli bacteruria. Please consider adding these as separate AEs. Please leave query open until events have been added to EDC or confirmed that they will not be added.' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 16:49:19

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Per medical records, subject was diagnosed with right sided heart failure and E.coli bacteriuria. Please consider adding these as separate AEs. Please leave query open until events have been added to EDC or confirmed that they will not be added.' answered with 'Pending medical records regarding right sided heart failure and E. coli bacteriuria. Will updated when received. ' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 22:25:00
User opened query 'PV Query: Per medical records, subject was diagnosed with right sided heart failure and E.coli bacteriuria. Please consider adding these as separate AEs. Please leave query open until events have been added to EDC or confirmed that they will not be added.' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 19:35:01
User closed query 'PV Query: Per medical records, subject was diagnosed with right sided heart failure and E.coli bacteriuria. Please consider adding these as separate AEs. ' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 19:35:01
Query 'PV Query: Per medical records, subject was diagnosed with right sided heart failure and E.coli bacteriuria. Please consider adding these as separate AEs. ' answered with 'pending medical records. Will add both AE's when records are obtained' (Site from Safety).	Gordon Bovee (b) (4) (b) (4)	22 Apr 2021 00:21:01
User closed query 'PV Query: Please confirm the subject's symptoms that are still ongoing. ' (Site from Safety).	(b) (4), (b) (6)	20 Apr 2021 13:53:19
Query 'PV Query: Please confirm the subject's symptoms that are still ongoing. ' answered with 'symptoms not ongoing.' (Site from Safety).	Gordon Bovee (b) (4) (b) (4)	19 Apr 2021 17:34:23
User opened query 'PV Query: Please confirm the subject's symptoms that are still ongoing. ' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 14:11:34
User opened query 'PV Query: Per medical records, subject was diagnosed with right sided heart failure and E.coli bacteriuria. Please consider adding these as separate AEs. ' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 14:11:20
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:29:12

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Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable ' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 13:28:04
User closed query 'PV Query: Please provide date of COVID test if available. ' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 13:28:01
User closed query 'PV Query: Please provide details on 99% occlusion and corresponding test results. ' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 13:27:59
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable ' answered with 'updated' (Site from Safety).	He (Helen) Pu (b) (4)	09 Apr 2021 19:29:55
Query 'PV Query: Please provide date of COVID test if available. ' answered with 'updated' (Site from Safety).	He (Helen) Pu (b) (4)	09 Apr 2021 19:29:52
Query 'PV Query: Please provide details on 99% occlusion and corresponding test results. ' answered with 'updated' (Site from Safety).	He (Helen) Pu (b) (4)	09 Apr 2021 19:29:50
DataPoint Un-verified.	He (Helen) Pu (b) (4)	09 Apr 2021 19:29:37

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Form: Adverse Events (2)

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Audit	User	Time (GMT)
User entered 'SUBJECT CALLED SITE TO REPORT ABOVE AE AND HOSPITALIZATION FROM 10/29/20 - ONGOING. SUBJECT IS ADMITTED AT UCSD, MEDICAL RECORDS WILL BE REQUESTED UPON SUBJECT'S RETURN TO SITE. SUBJECT DENIED ANY RECENT TRAVEL, SMOKER OR ORAL BC. SUBJECT REPORTED TWO NEGATIVE TESTS FOR COVID, PERFORMED IN HOSPITAL. PER SUBJECT, UNKNOWN CAUSE AT THIS TIME. SUBJECT STATED IT WAS 99% OCCLUDED.   09Apr2021 MR narrative updates: negative COVID-19 nasal swab collected on 30Oct2020 @ 0009. Diagnostic tests include chest x-rays (29Oct2020 & 02Nov2020), CTA pulmonary embolus (29Oct2020), and Ultrasound lower extremities venous duplex bilateral (30Oct2020). 29Oct2020 chest x-ray reports bronchial wall thickening and no evidence of pneumonia while 02Nov2020 chest x-ray shows streaky bibasal opacities (atelectasis or evolving infarcts). CTA pulmonary embolus revealed extensive nonocclusive bilateral pulmonary emboli within lobar and segmental pulmonary arteries (probable right heart strain). Lower extremity ultrasound showed no evidence of DVTs. D-Dimer collected twice on 29Oct2020: @ 1856: 3599 ng/mL (reference range <241 ng/mL) and @ 1935: 4487 ng/mL. Discharge summary reports no clear provoking factor for PE. Note subject had reported 99% occlusion but MR CTA reports PEs were non-occlusive.' reason for change: New Information	He (Helen) Pu (b) (4) (b) (4)	09 Apr 2021 19:29:37
Query 'Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' canceled (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 16:40:23
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable ' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 13:01:59

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Folder: Adverse Events

Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide date of COVID test if available.' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 13:01:50
User opened query 'PV Query: Please provide details on 99% occlusion and corresponding test results.' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 13:01:38
User opened query 'Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 13:01:25
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 20:02:46
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 20:02:10
User closed query 'PV Query: Please provide date of COVID test if available.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 20:01:48
User closed query 'PV Query: Please provide details on 99% occlusion and corresponding test results.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 20:01:42
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'subject notified site yesterday 23NOV2020 of hospital discharge. Medical records are pending at this moment' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 00:01:55
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable' answered with 'pending medical records review' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 22:44:53
Query 'PV Query: Please provide date of COVID test if available.' answered with 'pending medical records review' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 22:44:49

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Folder: Adverse Events

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Audit	User	Time (GMT)
Query 'PV Query: Please provide details on 99% occlusion and corresponding test results.' answered with 'pending medical records review' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 22:44:45
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 16:26:03
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 16:25:08
User opened query 'PV Query: Please provide date of COVID test if available.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 16:24:12
User opened query 'PV Query: Please provide details on 99% occlusion and corresponding test results.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 16:24:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:18:04
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	03 Nov 2020 20:37:59
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	03 Nov 2020 20:37:59
User entered 'Subject called site to report above AE and hospitalization from 10/29/20 - ongoing. Subject is admitted at UCSD, medical records will be requested upon subject's return to site. Subject denied any recent travel, smoker or oral BC. Subject reported two negative tests for COVID, performed in hospital. Per subject, unknown cause at this time. Subject stated it was 99% occluded.' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 20:37:59
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	03 Nov 2020 20:27:56
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 20:27:56

**US3732304**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Nov 2020 20:27:56

**US3732304**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 Nov 2020 20:27:56

**US3732304**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Apr 2021 18:29:07

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:26:54

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:32:03
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:22:55
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:55:08

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:26:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 10:16:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 10:16:38
Data point term sent to Coder	System	21 Sep 2020 16:59:13
User entered 'zyrtec'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:58:51

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:58:51



**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'pet dander and environmental allergies'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:58:51

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:26:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Dec 2020 23:36:03
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 19:36:57
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 00:19:40
User entered '10' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Nov 2020 00:19:35
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 22:27:15
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 15:33:46
User entered '3'	Lauren Arnett (b) (4)	21 Sep 2020 16:58:51
	(b) (4)	

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:26:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'mg (mg)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:58:51

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:26:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:58:51

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:26:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'as needed (PRN)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:58:51

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:26:54

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:58:51

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'Oral (ORAL)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:58:51

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:26:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:58:51



**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'un UNK 1978'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:58:51

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:58:51

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:58:51

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:26:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:58:51

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 16:58:51

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 16:58:51

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 16:58:51

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 16:58:51



US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:26:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 17:02:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 17:02:43
Data point term sent to Coder	System	21 Sep 2020 17:01:20
User entered 'albuterol'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:00:35

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:00:35

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'asthma'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:00:35

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:26:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered '90' reason for change: New Information	Amara Yilmaz (b) (4) (b) (4)	19 Oct 2020 16:43:52
User entered '1'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:00:35

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:26:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User closed query 'Per CDM: Dose Unit is recorded as 'Other - PUFF', however, please confirm if Unit can be selected from already available option PUFF . Thank you.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 10:14:32
Query 'Per CDM: Dose Unit is recorded as 'Other - PUFF', however, please confirm if Unit can be selected from already available option PUFF . Thank you.' answered with 'dose unit has been corrected ' (Site from DM).	Amara Yilmaz (b) (4)	19 Oct 2020 16:44:17
	(b) (4)	
User entered 'ug (ug)' reason for change: New Information	Amara Yilmaz (b) (4)	19 Oct 2020 16:43:52
	(b) (4)	
User opened query 'Per CDM: Dose Unit is recorded as 'Other - PUFF', however, please confirm if Unit can be selected from already available option PUFF . Thank you.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 12:45:13
User entered 'Other (OTHER)'	Lauren Arnett (b) (4)	21 Sep 2020 17:00:35
	(b) (4)	

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:26:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty; reason for change New Information	Amara Yilmaz (b) (4) (b) (4)	19 Oct 2020 16:43:52
User entered 'puff'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:00:35

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:26:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'as needed (PRN)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:00:35

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:26:54

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:00:35



US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:26:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:00:35

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:26:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:00:35

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'un UNK 1974'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:00:35

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:00:35

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:00:35

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:26:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:00:35

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:26:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:00:35

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 17:00:35



**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 17:00:35

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 17:00:35

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:26:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 17:02:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 17:02:44
Data point term sent to Coder	System	21 Sep 2020 17:01:20
User entered 'pantoprazole'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:01:13

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:26:54**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:01:13

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:26:54**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'gastroesophageal reflux disease'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:01:13

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:26:54**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered '20'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:01:13

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:26:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'mg (mg)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:01:13

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:26:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:01:13



US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:26:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'once daily (QD)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:01:13

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:26:54

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:01:13

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:26:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'Oral (ORAL)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:01:13

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:26:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:01:13

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:26:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'un UNK 1998'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:01:13

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:26:54**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:01:13

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:26:54**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:01:13

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:26:54**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:01:13



US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:26:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:01:13

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:26:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 17:01:13

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:26:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 17:01:13

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:26:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Sep 2020 17:01:13

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:26:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 17:03:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 17:03:49
Data point term sent to Coder	System	21 Sep 2020 17:02:22
User entered 'gabapentin'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:01:57

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:26:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:01:57

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:26:54**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'chronic back pain'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:01:57

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:26:54**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered '1200'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:01:57



US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:26:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'mg (mg)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:01:57

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:26:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:01:57

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:26:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'once daily (QD)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:01:57

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:26:54

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:01:57

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:26:54**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'Oral (ORAL)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:01:57

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:26:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:01:57

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:26:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'un UNK 2010'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:01:57

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:26:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:01:57



**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:26:54**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:01:57

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:26:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:01:57

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:26:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:01:57

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:26:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 17:01:57

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:26:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 17:01:57

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:26:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Sep 2020 17:01:57

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:26:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: NORCO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 17:04:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 17:04:40
Data point term sent to Coder	System	21 Sep 2020 17:03:24
User entered 'norco'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:02:35

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:26:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:02:35



**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:26:54**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'post surgical pain'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:02:35

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:26:54**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered '10/325'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:02:35

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:26:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'mg (mg)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:02:35

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:26:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:02:35

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:26:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'as needed (PRN)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:02:35

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:26:54

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:02:35

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:26:54**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'Oral (ORAL)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:02:35

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:26:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:02:35



US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:26:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'un UNK 2010'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:02:35

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:26:54**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:02:35

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:26:54**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:02:35

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:26:54**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:02:35

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:26:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:02:35

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:26:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 17:02:35

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:26:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 17:02:35

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:26:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 17:02:35



US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:26:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: ESTRADIOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 22:54:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 22:54:45
Data point term sent to Coder Coding entries removed.	System Lauren Arnett (b) (4) (b) (4)	03 Nov 2020 00:22:53 03 Nov 2020 00:22:01
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ESTROGENS, ATC: NATURAL AND SEMISYNTHETIC ESTROGENS, PLAIN, PRODUCT: ESTRADIOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 11:30:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 11:30:42
Data point term sent to Coder User entered 'estradiol 0.01% cream'	System Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:04:28 21 Sep 2020 17:03:38

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:26:54**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:03:38

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:26:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 19:37:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'entry error updated' (Site from DM).	Lauren Arnett (b) (4)	03 Nov 2020 00:22:31
User entered 'peri-menopause' reason for change: Per Query Resolution	(b) (4)	03 Nov 2020 00:22:01
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 15:34:39
User entered 'frequent urinary tract infections'	Lauren Arnett (b) (4)	21 Sep 2020 17:03:38

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:26:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'I'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:03:38

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:26:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'Other (OTHER)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:03:38

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:26:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'pump'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:03:38

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:26:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'every other day (QOD)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:03:38

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:26:54

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:03:38



**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:26:54**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'Topical (TOPICAL)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:03:38

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:26:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:03:38

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:26:54**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'un UNK 2017'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:03:38

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:26:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:03:38

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:26:54**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:03:38

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:26:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:03:38

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:26:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:03:38

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:26:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 17:03:38



**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:26:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	21 Sep 2020 17:03:38

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:26:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Sep 2020 17:03:38

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:26:54

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:50
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: OTHER GYNECOLOGICALS, ATC: CONTRACEPTIVES FOR TOPICAL USE, ATC: INTRAVAGINAL CONTRACEPTIVES, PRODUCT: ETHINYLESTRADIOL;ETONOGESTREL, PRODUCTSYNONYM: NUVARING - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Nov 2020 14:34:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Nov 2020 14:34:02
Data point term sent to Coder	System	07 Nov 2020 00:18:18
Coding entries removed.	(b) (4), (b) (6)	07 Nov 2020 00:18:10
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: OTHER GYNECOLOGICALS, ATC: CONTRACEPTIVES FOR TOPICAL USE, ATC: INTRAVAGINAL CONTRACEPTIVES, PRODUCT: ETHINYLESTRADIOL;ETONOGESTREL, PRODUCTSYNONYM: NUVARING - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Sep 2020 17:05:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Sep 2020 17:05:43
Data point term sent to Coder	System	21 Sep 2020 17:04:30
User entered 'nuva ring'	Lauren Arnett (b) (4)	21 Sep 2020 17:04:18

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:26:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:50
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 23:36:40
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 19:38:03
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 00:18:17
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Nov 2020 00:18:10
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 22:29:02
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 15:35:26
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:04:18

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:26:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:50
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Dec 2020 23:36:45
DataPoint Un-verified.	(b) (4), (b) (6)	07 Nov 2020 00:18:10
User entered 'Pregnancy' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Nov 2020 00:18:10
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'birth control'	Lauren Arnett (b) (4)	21 Sep 2020 17:04:18
	(b) (4)	

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:26:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:50
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User closed query 'Per DM CLR: Please update the DOSE and UNIT entries for this combination drug to list the specific doses for each component rather than a number of rings. Please verify the dose and unit, and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 13:40:43
Query 'Per DM CLR: Please update the DOSE and UNIT entries for this combination drug to list the specific doses for each component rather than a number of rings. Please verify the dose and unit, and update as appropriate. ' answered with 'confirmed with subject that this was correct dosage' (Site from DM).	Gordon Bovee (b) (4)	16 Feb 2021 20:18:42
User opened query 'Per DM CLR: Please update the DOSE and UNIT entries for this combination drug to list the specific doses for each component rather than a number of rings. Please verify the dose and unit, and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 02:15:13
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered '1'	Lauren Arnett (b) (4)	21 Sep 2020 17:04:18

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:26:54**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:50
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'Other (OTHER)'	Lauren Arnett (b) (4)	21 Sep 2020 17:04:18
	(b) (4)	

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:26:54**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:50
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'ring'	Lauren Arnett (b) (4)	21 Sep 2020 17:04:18
	(b) (4)	



US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:26:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:50
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User closed query 'Per DM CLR: Please review the Frequency and Route of Administration as this medication is not typically administered as indicated. Please update the Frequency and Route as appropriate. Otherwise, please provide clarification.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 13:40:50
Query 'Per DM CLR: Please review the Frequency and Route of Administration as this medication is not typically administered as indicated. Please update the Frequency and Route as appropriate. Otherwise, please provide clarification.' answered with 'confirmed with subject that this was correct' (Site from DM).	Gordon Bovee (b) (4)	16 Feb 2021 20:19:01
User opened query 'Per DM CLR: Please review the Frequency and Route of Administration as this medication is not typically administered as indicated. Please update the Frequency and Route as appropriate. Otherwise, please provide clarification.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 02:15:34
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'every month (QM)'	Lauren Arnett (b) (4)	21 Sep 2020 17:04:18

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:26:54**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:50
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4)	21 Sep 2020 17:04:18
	(b) (4)	

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:26:54**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:50
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'Vaginal (VAGINAL)'	Lauren Arnett (b) (4)	21 Sep 2020 17:04:18
	(b) (4)	

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:26:54**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:50
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4)	21 Sep 2020 17:04:18
	(b) (4)	

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:26:54**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:50
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'un UNK 2018'	Lauren Arnett (b) (4)	21 Sep 2020 17:04:18
	(b) (4)	

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:26:54**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:50
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered '0'	Lauren Arnett (b) (4)	21 Sep 2020 17:04:18
	(b) (4)	

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:26:54**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 21:07:06
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Un-verified.	(b) (4) Gordon Bovee (b) (4)	16 Feb 2021 20:18:10
User entered 'No (N)' reason for change: New Information	Gordon Bovee (b) (4)	16 Feb 2021 20:18:10
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	21 Sep 2020 17:04:18

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:26:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:50
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 21:07:08
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Un-verified.	Gordon Bovee (b) (4)	16 Feb 2021 20:18:10
User entered '11 Nov 2020' reason for change: New Information	Gordon Bovee (b) (4)	16 Feb 2021 20:18:10
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4)	21 Sep 2020 17:04:18



**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:26:54**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:50
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'No (N)'	Lauren Arnett (b) (4)	21 Sep 2020 17:04:18
	(b) (4)	

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:26:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:50
User entered '1'	System	21 Sep 2020 17:04:18

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:26:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:50
User entered '1'	System	21 Sep 2020 17:04:18

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:26:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:50
User entered '802 (802)'	System	21 Sep 2020 17:04:18

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:26:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: NON-SELECTIVE MONOAMINE REUPTAKE INHIBITORS, PRODUCT: AMITRIPTYLINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 21:42:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 21:42:54
Data point term sent to Coder	System	21 Sep 2020 17:10:45
User entered 'amitriptyline'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:09:47

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:26:54**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:09:47

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:26:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'depression / insomnia'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:09:47

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:26:54**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered '10'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:09:47



US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:26:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'mg (mg)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:09:47

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:26:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:09:47

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:26:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'once daily (QD)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:09:47

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:26:54

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:09:47

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:26:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'Oral (ORAL)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:09:47

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:26:54**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:09:47

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:26:54**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'un UNK 1996'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:09:47

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:26:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:09:47



**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:26:54**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:09:47

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:26:54**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:09:47

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:26:54**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:09:47

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:26:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 17:09:47

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:26:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 17:09:47

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:26:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Sep 2020 17:09:47

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:26:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: FLUOXETINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 17:11:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 17:11:49
Data point term sent to Coder	System	21 Sep 2020 17:10:46
User entered 'fluoxetine'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:10:25

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:26:54**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:10:25



US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:26:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'depression'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:10:25

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:26:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered '50'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:10:25

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:26:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'mg (mg)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:10:25

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:26:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:10:25

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:26:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'once daily (QD)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:10:25

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:26:54

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:10:25

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:26:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'Oral (ORAL)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:10:25

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:26:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:10:25



US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:26:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'un UNK 1996'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:10:25

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:26:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:10:25

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:26:54**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:10:25

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:26:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:10:25

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:26:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:10:25

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:26:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 17:10:25

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:26:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 17:10:25

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:26:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Sep 2020 17:10:25



US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:26:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: BUPROPION HYDROCHLORIDE, PRODUCTSYNONYM: WELLBUTRIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 17:12:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 17:12:52
Data point term sent to Coder	System	21 Sep 2020 17:11:47
User entered 'wellbutrin'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:11:01

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:26:54**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:11:01

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:26:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'depression'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:11:01

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:26:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered '450'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:11:01

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:26:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'mg (mg)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:11:01

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:26:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:11:01

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:26:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'once daily (QD)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:11:01

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:26:54

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:11:01



**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:26:54**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'Oral (ORAL)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:11:01

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:26:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:11:01

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:26:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'un UNK 1996'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:11:01

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:26:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:11:01

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:26:54**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:11:01

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:26:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:11:01

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:26:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:11:01

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:26:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 17:11:01



**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:26:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 17:11:01

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:26:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Sep 2020 17:11:01

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:26:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	10 Nov 2020 05:44:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 05:44:28
Data point term sent to Coder	System	07 Nov 2020 00:22:20
Coding entries removed.	(b) (4), (b) (6)	07 Nov 2020 00:21:51
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 17:12:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 17:12:52
Data point term sent to Coder	System	21 Sep 2020 17:11:48
User entered 'magnesium'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:11:40

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:26:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Dec 2020 23:37:05
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate.	(b) (4), (b) (6)	10 Nov 2020 19:38:26
' (Site from DM).		
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate.	(b) (4), (b) (6)	07 Nov 2020 00:21:58
' answered with 'updated' (Site from DM).		
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Nov 2020 00:21:51
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 22:29:23
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate.	(b) (4), (b) (6)	01 Nov 2020 15:36:00
' (Site from DM).		
User entered 'No (N)'	Lauren Arnett (b) (4)	21 Sep 2020 17:11:40
	(b) (4)	

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:26:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User closed query 'Per DM CLR: Prophylaxis is marked as YES. However, please confirm whether there is an existing actual condition of Vitamin Deficiency requiring this medication. If yes, please ensure that there is a corresponding MH/AE condition recorded that matches this medication and review if the prophylaxis field should be changed to NO, as appropriate. Otherwise, provide clarification. '(Site from DM).	(b) (4), (b) (6)	08 Feb 2021 15:06:27
Query 'Per DM CLR: Prophylaxis is marked as YES. However, please confirm whether there is an existing actual condition of Vitamin Deficiency requiring this medication. If yes, please ensure that there is a corresponding MH/AE condition recorded that matches this medication and review if the prophylaxis field should be changed to NO, as appropriate. Otherwise, provide clarification. ' answered with 'subject is taking magnesium as prophylaxis' (Site from DM).	Gordon Bovee (b) (4)	06 Feb 2021 00:29:08
User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, please confirm whether there is an existing actual condition of Vitamin Deficiency requiring this medication. If yes, please ensure that there is a corresponding MH/AE condition recorded that matches this medication and review if the prophylaxis field should be changed to NO, as appropriate. Otherwise, provide clarification. '(Site from DM).	(b) (4), (b) (6)	26 Jan 2021 02:16:03
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 23:37:07
DataPoint Un-verified.	(b) (4), (b) (6)	07 Nov 2020 00:21:51
User entered 'VITAMIN deficiency' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Nov 2020 00:21:51
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'vitamin supplement'	Lauren Arnett (b) (4)	21 Sep 2020 17:11:40

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:26:54

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 21:08:39
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 16:20:40
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'updated' (Site from DM).	Gordon Bovee (b) (4)	16 Feb 2021 20:12:35
DataPoint Un-verified.	Gordon Bovee (b) (4)	16 Feb 2021 20:12:27
User entered '160' reason for change: New Information	Gordon Bovee (b) (4)	16 Feb 2021 20:12:27
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 02:16:12
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered '1'	Lauren Arnett (b) (4)	21 Sep 2020 17:11:40

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:26:54

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 21:08:41
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Un-verified.	Gordon Bovee (b) (4)	16 Feb 2021 20:12:27
User entered 'mg (mg)' reason for change: New Information	Gordon Bovee (b) (4)	16 Feb 2021 20:12:27
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'tablet (TABLET)'	Lauren Arnett (b) (4)	21 Sep 2020 17:11:40

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:26:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:11:40



US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:26:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'once daily (QD)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:11:40

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:26:54

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:11:40

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:26:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'Oral (ORAL)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:11:40

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:26:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:11:40

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:26:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'un UNK 1998'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:11:40

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:26:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered '0'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:11:40

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:26:54**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:11:40

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:26:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:11:40



US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:26:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	21 Sep 2020 17:11:40

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:26:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 17:11:40

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:26:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 17:11:40

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:26:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Sep 2020 17:11:40

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:26:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	07 Nov 2020 00:23:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Nov 2020 00:23:23
Data point term sent to Coder	System	07 Nov 2020 00:22:20
Coding entries removed.	(b) (4), (b) (6)	07 Nov 2020 00:22:08
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Sep 2020 19:11:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Sep 2020 19:11:51
Data point term sent to Coder	System	22 Sep 2020 19:10:21
User entered 'multivitamin'	Lauren Arnett (b) (4)	22 Sep 2020 19:09:31

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:26:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Dec 2020 23:37:13
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 19:38:41
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 00:22:13
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Nov 2020 00:22:08
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 22:29:43
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 15:36:33
User entered 'No (N)'	Lauren Arnett (b) (4)	22 Sep 2020 19:09:31
	(b) (4)	

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:26:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User closed query 'Per DM CLR: Prophylaxis is marked as YES. However, please confirm whether there is an existing actual condition of Vitamin Deficiency requiring this medication. If yes, please ensure that there is a corresponding MH/AE condition recorded that matches this medication and review if the prophylaxis field should be changed to NO, as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 15:06:48
Query 'Per DM CLR: Prophylaxis is marked as YES. However, please confirm whether there is an existing actual condition of Vitamin Deficiency requiring this medication. If yes, please ensure that there is a corresponding MH/AE condition recorded that matches this medication and review if the prophylaxis field should be changed to NO, as appropriate. Otherwise, provide clarification.' answered with 'subject is taking multivitamin as prophylaxis' (Site from DM).	Gordon Bovee (b) (4)	06 Feb 2021 00:30:29
User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, please confirm whether there is an existing actual condition of Vitamin Deficiency requiring this medication. If yes, please ensure that there is a corresponding MH/AE condition recorded that matches this medication and review if the prophylaxis field should be changed to NO, as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 02:16:27
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 23:37:15
DataPoint Un-verified.	(b) (4), (b) (6)	07 Nov 2020 00:22:08
User entered 'VITAMIN deficiency' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Nov 2020 00:22:08
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'vitamin supplement'	Lauren Arnett (b) (4)	22 Sep 2020 19:09:31

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:26:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'I'	Lauren Arnett (b) (4) (b) (4)	22 Sep 2020 19:09:31



US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:26:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'tablet (TABLET)'	Lauren Arnett (b) (4) (b) (4)	22 Sep 2020 19:09:31

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:26:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	22 Sep 2020 19:09:31

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:26:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'once daily (QD)'	Lauren Arnett (b) (4) (b) (4)	22 Sep 2020 19:09:31

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:26:54

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	22 Sep 2020 19:09:31

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:26:54**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'Oral (ORAL)'	Lauren Arnett (b) (4) (b) (4)	22 Sep 2020 19:09:31

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:26:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	22 Sep 2020 19:09:31

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:26:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'un UNK 1998'	Lauren Arnett (b) (4) (b) (4)	22 Sep 2020 19:09:31

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:26:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered '0'	Lauren Arnett (b) (4) (b) (4)	22 Sep 2020 19:09:31



**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:26:54**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	22 Sep 2020 19:09:31

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:26:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Lauren Arnett (b) (4) (b) (4)	22 Sep 2020 19:09:31

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:26:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	22 Sep 2020 19:09:31

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:26:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 19:09:31

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:26:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 19:09:31

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:26:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Sep 2020 19:09:31

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:26:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Nov 2020 00:24:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Nov 2020 00:24:23
Data point term sent to Coder	System	07 Nov 2020 00:23:20
Coding entries removed.	(b) (4), (b) (6)	07 Nov 2020 00:22:25
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Sep 2020 17:22:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Sep 2020 17:22:53
Data point term sent to Coder	System	24 Sep 2020 17:21:14
User entered 'vitamin D3'	Amara Yilmaz (b) (4)	24 Sep 2020 17:20:38

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:26:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 23:37:38
DataPoint Un-verified.	(b) (4), (b) (6)	07 Nov 2020 00:22:25
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Nov 2020 00:22:25
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'No (N)'	Amara Yilmaz (b) (4) (b) (4)	24 Sep 2020 17:20:38



US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:26:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User closed query 'Per DM CLR: Prophylaxis is marked as YES. However, please confirm whether there is an existing actual condition of Vitamin Deficiency requiring this medication. If yes, please ensure that there is a corresponding MH/AE condition recorded that matches this medication and review if the prophylaxis field should be changed to NO, as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 15:07:09
Query 'Per DM CLR: Prophylaxis is marked as YES. However, please confirm whether there is an existing actual condition of Vitamin Deficiency requiring this medication. If yes, please ensure that there is a corresponding MH/AE condition recorded that matches this medication and review if the prophylaxis field should be changed to NO, as appropriate. Otherwise, provide clarification.' answered with 'subject is taking vitamin d3 as prophylaxis' (Site from DM).	Gordon Bovee (b) (4)	06 Feb 2021 00:30:50
User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, please confirm whether there is an existing actual condition of Vitamin Deficiency requiring this medication. If yes, please ensure that there is a corresponding MH/AE condition recorded that matches this medication and review if the prophylaxis field should be changed to NO, as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 02:16:38
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 23:37:39
DataPoint Un-verified.	(b) (4), (b) (6)	07 Nov 2020 00:22:25
User entered 'VITAMIN deficiency' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Nov 2020 00:22:25
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'vitamin supplement'	Amara Yilmaz (b) (4)	24 Sep 2020 17:20:38

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:26:54

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 21:09:28
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 16:21:12
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'updated' (Site from DM).	Gordon Bovee (b) (4)	16 Feb 2021 20:13:30
DataPoint Un-verified.	Gordon Bovee (b) (4)	16 Feb 2021 20:13:22
User entered '1600' reason for change: New Information	Gordon Bovee (b) (4)	16 Feb 2021 20:13:22
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 02:16:46
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'I'	Amara Yilmaz (b) (4)	24 Sep 2020 17:20:38

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:26:54

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 21:09:51
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Un-verified.	Gordon Bovee (b) (4)	16 Feb 2021 20:13:22
User entered 'IU (IU)' reason for change: New Information	Gordon Bovee (b) (4)	16 Feb 2021 20:13:22
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'tablet (TABLET)'	Amara Yilmaz (b) (4)	24 Sep 2020 17:20:38

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:26:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	24 Sep 2020 17:20:38

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:26:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'once daily (QD)'	Amara Yilmaz (b) (4) (b) (4)	24 Sep 2020 17:20:38

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:26:54

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	24 Sep 2020 17:20:38

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:26:54**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'Oral (ORAL)'	Amara Yilmaz (b) (4) (b) (4)	24 Sep 2020 17:20:38

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:26:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	24 Sep 2020 17:20:38



US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:26:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'un UNK 1998'	Amara Yilmaz (b) (4) (b) (4)	24 Sep 2020 17:20:38

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:26:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered '0'	Amara Yilmaz (b) (4) (b) (4)	24 Sep 2020 17:20:38

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:26:54**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'Yes (Y)'	Amara Yilmaz (b) (4) (b) (4)	24 Sep 2020 17:20:38

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:26:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	24 Sep 2020 17:20:38

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:26:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'No (N)'	Amara Yilmaz (b) (4) (b) (4)	24 Sep 2020 17:20:38

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:26:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Sep 2020 17:20:38

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:26:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Sep 2020 17:20:38

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:26:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Sep 2020 17:20:38



US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:26:54

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: ZINC, PRODUCT: ZINC - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	07 Nov 2020 00:25:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Nov 2020 00:25:24
Data point term sent to Coder	System	07 Nov 2020 00:24:23
Coding entries removed.	(b) (4), (b) (6)	07 Nov 2020 00:23:40
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: ZINC, PRODUCT: ZINC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Sep 2020 17:22:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Sep 2020 17:22:54
Data point term sent to Coder	System	24 Sep 2020 17:22:17
User entered 'Zinc'	Amara Yilmaz (b) (4)	24 Sep 2020 17:21:48

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:26:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Dec 2020 23:37:52
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 19:38:53
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 00:23:46
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Nov 2020 00:23:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 22:30:11
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 15:41:09
User entered 'No (N)'	Amara Yilmaz (b) (4)	24 Sep 2020 17:21:48
	(b) (4)	

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:26:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User closed query 'Per DM CLR: Prophylaxis is marked as YES. However, please confirm whether there is an existing actual condition of Vitamin Deficiency requiring this medication. If yes, please ensure that there is a corresponding MH/AE condition recorded that matches this medication and review if the prophylaxis field should be changed to NO, as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 15:07:31
Query 'Per DM CLR: Prophylaxis is marked as YES. However, please confirm whether there is an existing actual condition of Vitamin Deficiency requiring this medication. If yes, please ensure that there is a corresponding MH/AE condition recorded that matches this medication and review if the prophylaxis field should be changed to NO, as appropriate. Otherwise, provide clarification.' answered with 'subject is taking zinc as prophylaxis' (Site from DM).	Gordon Bovee (b) (4)	06 Feb 2021 00:31:36
User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, please confirm whether there is an existing actual condition of Vitamin Deficiency requiring this medication. If yes, please ensure that there is a corresponding MH/AE condition recorded that matches this medication and review if the prophylaxis field should be changed to NO, as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 02:17:00
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 23:37:55
DataPoint Un-verified.	(b) (4), (b) (6)	07 Nov 2020 00:23:40
User entered 'VITAMIN deficiency' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Nov 2020 00:23:40
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'vitamin supplement'	Amara Yilmaz (b) (4)	24 Sep 2020 17:21:48

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:26:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Dec 2020 23:37:57
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 19:39:00
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'updated. entry error' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 00:23:54
User entered '100' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Nov 2020 00:23:40
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 22:30:26
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 15:41:42
User entered '1'	Amara Yilmaz (b) (4)	24 Sep 2020 17:21:48
	(b) (4)	

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:26:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 23:38:00
DataPoint Un-verified.	(b) (4), (b) (6)	07 Nov 2020 00:23:40
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Nov 2020 00:23:40
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'tablet (TABLET)'	Amara Yilmaz (b) (4) (b) (4)	24 Sep 2020 17:21:48

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:26:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	24 Sep 2020 17:21:48

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:26:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'once daily (QD)'	Amara Yilmaz (b) (4) (b) (4)	24 Sep 2020 17:21:48

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:26:54

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	24 Sep 2020 17:21:48



**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:26:54**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'Oral (ORAL)'	Amara Yilmaz (b) (4) (b) (4)	24 Sep 2020 17:21:48

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:26:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	24 Sep 2020 17:21:48

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:26:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'un UNK 1998'	Amara Yilmaz (b) (4) (b) (4)	24 Sep 2020 17:21:48

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:26:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered '0'	Amara Yilmaz (b) (4) (b) (4)	24 Sep 2020 17:21:48

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:26:54**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'Yes (Y)'	Amara Yilmaz (b) (4) (b) (4)	24 Sep 2020 17:21:48

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:26:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	24 Sep 2020 17:21:48

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:26:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'No (N)'	Amara Yilmaz (b) (4) (b) (4)	24 Sep 2020 17:21:48

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:26:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Sep 2020 17:21:48



**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:26:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Sep 2020 17:21:48

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:26:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Sep 2020 17:21:48

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:26:54

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:54
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:26:57
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 05:05:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 05:05:18
Data point term sent to Coder	System	03 Nov 2020 20:45:46
User entered 'heparin'	(b) (4), (b) (6)	03 Nov 2020 20:45:04

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:26:54**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:54
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 20:45:04

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:26:54**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:54
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'bilateral pulmonary embolism'	(b) (4), (b) (6)	03 Nov 2020 20:45:04

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:26:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:54
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User closed query 'Per DM CLR: Please provide dose in units instead of ML, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 16:23:33
Query 'Per DM CLR: Please provide dose in units instead of ML, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'updated' (Site from DM).	Gordon Bovee (b) (4)	16 Feb 2021 20:14:25
User opened query 'Per DM CLR: Please provide dose in units instead of ML, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 07:53:03
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered '50'	(b) (4), (b) (6)	03 Nov 2020 20:45:04

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:26:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:54
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 21:10:06
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Un-verified.	(b) (4) Gordon Bovee (b) (4)	16 Feb 2021 20:14:15
User entered 'IU (IU)' reason for change: New Information	(b) (4) Gordon Bovee (b) (4)	16 Feb 2021 20:14:15
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'mL (mL)'	(b) (4), (b) (6)	03 Nov 2020 20:45:04

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:26:54**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:54
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 20:45:04



**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:26:54**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:54
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'other (OTHER)'	(b) (4), (b) (6)	03 Nov 2020 20:45:04

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:26:54**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:54
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'drip'	(b) (4), (b) (6)	03 Nov 2020 20:45:04

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:26:54**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:54
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	(b) (4), (b) (6)	03 Nov 2020 20:45:04

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:26:54**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:54
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 20:45:04

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:26:54**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:54
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered '29 Oct 2020'	(b) (4), (b) (6)	03 Nov 2020 20:45:04

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:26:54**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:54
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered '0'	(b) (4), (b) (6)	03 Nov 2020 20:45:04

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:26:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:54
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Dec 2020 23:38:08
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 22:49:56
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 22:49:56
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Nov 2020 20:45:04

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:26:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:54
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Dec 2020 23:38:11
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 22:49:56
User entered '03 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 22:49:56
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 20:45:04



**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:26:54**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:54
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:26:57
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 20:45:04

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:26:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:54
User entered empty.	System	03 Nov 2020 20:45:04

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:26:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:54
User entered empty.	System	03 Nov 2020 20:45:04

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:26:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:54
User entered empty.	System	03 Nov 2020 20:45:04

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:26:54

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 23:38:31
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)	24 Nov 2020 23:53:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 23:53:58
Data point term sent to Coder	System	24 Nov 2020 22:51:26
User entered 'Eloquis'	(b) (4), (b) (6)	24 Nov 2020 22:50:51

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:26:54**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 23:38:33
User entered 'No (N)'	(b) (4), (b) (6)	24 Nov 2020 22:50:51

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:26:54**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 23:38:34
User entered 'SAE- Bilateral Pulmonary Embolism'	(b) (4), (b) (6)	24 Nov 2020 22:50:51

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:26:54**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Dec 2020 23:38:37
User entered '5'	(b) (4), (b) (6)	24 Nov 2020 22:50:51



**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:26:54**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 23:38:38
User entered 'mg (mg)'	(b) (4), (b) (6)	24 Nov 2020 22:50:51

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:26:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 23:38:40
User entered empty.	(b) (4), (b) (6)	24 Nov 2020 22:50:51

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:26:54**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 23:38:41
User entered 'twice daily (BID)'	(b) (4), (b) (6)	24 Nov 2020 22:50:51

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:26:54

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 23:38:42
User entered empty.	(b) (4), (b) (6)	24 Nov 2020 22:50:51

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:26:54**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 23:38:44
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	24 Nov 2020 22:50:51

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:26:54**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 23:38:45
User entered empty.	(b) (4), (b) (6)	24 Nov 2020 22:50:51

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:26:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 23:38:47
User entered '03 Nov 2020'	(b) (4), (b) (6)	24 Nov 2020 22:50:51

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:26:54**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 23:38:49
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 22:50:51



**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:26:54**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 23:38:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Nov 2020 22:50:51

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:26:54**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 23:38:51
User entered empty.	(b) (4), (b) (6)	24 Nov 2020 22:50:51

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:26:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User closed query 'Per ConMed Log, Please Add "Naproxen" to eCRF Page.' (Site from CRA).	(b) (4), (b) (6)	10 Mar 2021 21:10:39
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
Query 'Per ConMed Log, Please Add "Naproxen" to eCRF Page.' answered with 'naproxen added' (Site from CRA).	Gordon Bovee (b) (4)	08 Jan 2021 18:59:49
User opened query 'Per ConMed Log, Please Add "Naproxen" to eCRF Page.' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 23:43:54
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 23:38:53
User entered 'No (N)'	(b) (4), (b) (6)	24 Nov 2020 22:50:51

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:26:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	24 Nov 2020 22:50:51

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:26:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 22:50:51

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:26:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Nov 2020 22:50:51

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:26:54

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:56
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 21:11:15
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Jan 2021 19:00:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Jan 2021 19:00:47
Data point term sent to Coder	System	08 Jan 2021 18:59:53
User entered 'Naproxen'	Gordon Bovee (b) (4) (b) (4)	08 Jan 2021 18:59:14

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:26:54**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:56
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 21:11:15
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered 'No (N)'	(b) (4) Gordon Bovee (b) (4) (b) (4)	08 Jan 2021 18:59:14



**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:26:54**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:56
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 21:11:15
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered 'chronic back pain'	(b) (4) Gordon Bovee (b) (4) (b) (4)	08 Jan 2021 18:59:14

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:26:54**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:56
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 21:11:15
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered '500'	(b) (4) Gordon Bovee (b) (4) (b) (4)	08 Jan 2021 18:59:14

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:26:54**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:56
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 21:11:15
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered 'mg (mg)'	(b) (4) Gordon Bovee (b) (4) (b) (4)	08 Jan 2021 18:59:14

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:26:54**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:56
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 21:11:15
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered empty.	Gordon Bovee (b) (4)	08 Jan 2021 18:59:14

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:26:54**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:56
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 21:11:15
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered 'twice daily (BID)'	Gordon Bovee (b) (4)	08 Jan 2021 18:59:14

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:26:54**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:56
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 21:11:15
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered empty.	(b) (4) Gordon Bovee (b) (4) (b) (4)	08 Jan 2021 18:59:14

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:26:54**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:56
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 21:11:15
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered 'Oral (ORAL)'	(b) (4) Gordon Bovee (b) (4) (b) (4)	08 Jan 2021 18:59:14

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:26:54**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:56
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 21:11:15
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered empty.	Gordon Bovee (b) (4)	08 Jan 2021 18:59:14



**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:26:54**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:56
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 21:11:15
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered 'un UNK 2010'	(b) (4) Gordon Bovee (b) (4) (b) (4)	08 Jan 2021 18:59:14

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:26:54**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:56
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 21:11:15
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered '0'	Gordon Bovee (b) (4)	08 Jan 2021 18:59:14

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:26:54**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:56
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 21:11:15
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered 'No (N)'	(b) (4) Gordon Bovee (b) (4) (b) (4)	08 Jan 2021 18:59:14

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:26:54**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:56
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 21:11:15
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered '29 Oct 2020'	(b) (4) Gordon Bovee (b) (4) (b) (4)	08 Jan 2021 18:59:14

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:26:54**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:56
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 21:11:15
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered 'No (N)'	(b) (4) Gordon Bovee (b) (4) (b) (4)	08 Jan 2021 18:59:14

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:26:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:56
User entered '2'	System	08 Jan 2021 18:59:14

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:26:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:56
User entered '1'	System	08 Jan 2021 18:59:14

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:26:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:43:56
User entered '804 (804)'	System	08 Jan 2021 18:59:14



US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:26:54

Name of Medication

Audit	User	Time (GMT)
User closed query 'Per CDM CR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening CHRONIC BACK PAIN should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 06:26:28
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
Query 'Per CDM CR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening CHRONIC BACK PAIN should be recorded, and update con med indication or provide clarification. ' answered with 'confirmed with patient today that the condition has not worsened. same medication has been taken in the past (since 2010) though not in a while (not capturable as CM at study start).'	He (Helen) Pu (b) (4)	09 Apr 2021 19:36:51
User opened query 'Per CDM CR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening CHRONIC BACK PAIN should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 14:03:44
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 21:11:18
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	05 Mar 2021 23:14:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	05 Mar 2021 23:14:01
Data point term sent to Coder	System	05 Mar 2021 23:13:16
User entered 'cyclobenzaprine'	Gordon Bovee (b) (4)	05 Mar 2021 23:12:47

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EAB) (1725)

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**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:26:54**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 21:11:18
User entered 'No (N)'	Gordon Bovee (b) (4)	05 Mar 2021 23:12:47
	(b) (4)	

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:26:54**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 21:11:18
User entered 'chronic back pain'	Gordon Bovee (b) (4)	05 Mar 2021 23:12:47
	(b) (4)	

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:26:54**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 21:11:18
User entered '10'	Gordon Bovee (b) (4)	05 Mar 2021 23:12:47
	(b) (4)	

US3732304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:26:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 21:11:18
User entered 'mg (mg)'	Gordon Bovee (b) (4)	05 Mar 2021 23:12:47

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:26:54**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 21:11:18
User entered empty.	Gordon Bovee (b) (4) (b) (4)	05 Mar 2021 23:12:47

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:26:54**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 21:11:18
User entered 'twice daily (BID)'	Gordon Bovee (b) (4)	05 Mar 2021 23:12:47
	(b) (4)	

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:26:54**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 21:11:18
User entered empty.	Gordon Bovee (b) (4) (b) (4)	05 Mar 2021 23:12:47



**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:26:54**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 21:11:18
User entered 'Oral (ORAL)'	Gordon Bovee (b) (4)	05 Mar 2021 23:12:47
	(b) (4)	

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:26:54**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 21:11:18
User entered empty.	Gordon Bovee (b) (4) (b) (4)	05 Mar 2021 23:12:47

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:26:54**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 21:11:18
User entered '22 Feb 2021'	Gordon Bovee (b) (4) (b) (4)	05 Mar 2021 23:12:47

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:26:54**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 21:11:18
User entered '0'	Gordon Bovee (b) (4)	05 Mar 2021 23:12:47
	(b) (4)	

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:26:54**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 21:11:18
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	05 Mar 2021 23:12:47
	(b) (4)	

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:26:54**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 21:11:18
User entered empty.	Gordon Bovee (b) (4)	05 Mar 2021 23:12:47
	(b) (4)	

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:26:54**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 21:11:18
User entered 'No (N)'	Gordon Bovee (b) (4)	05 Mar 2021 23:12:47
	(b) (4)	

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:26:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	05 Mar 2021 23:12:47



**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:26:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Mar 2021 23:12:47

**US3732304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:26:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Mar 2021 23:12:47

US3732304

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:26:54

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:32:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 22:39:16
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
User entered 'Yes (Y)' reason for change: New Information	(b) (4) He (Helen) Pu (b) (4)	09 Apr 2021 20:55:07
User entered 'No (N)'	(b) (4) Gordon Bovee (b) (4)	15 Mar 2021 18:49:33

**US3732304**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 09:26:54**

**Procedure/Surgery date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:23:21
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
User entered '29 Oct 2020'	He (Helen) Pu (b) (4)	09 Apr 2021 20:55:22

US3732304

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:26:54

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:23:21
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
User entered 'chest x-ray'	He (Helen) Pu (b) (4)	09 Apr 2021 20:55:22

**US3732304**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:23:21
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) He (Helen) Pu (b) (4) (b) (4)	09 Apr 2021 20:55:22

**US3732304**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 09:26:54**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:23:21
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
User entered empty.	(b) (4) He (Helen) Pu (b) (4)	09 Apr 2021 20:55:22
	(b) (4)	

US3732304

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:26:54

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:23:22
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
User entered '29 Oct 2020'	(b) (4) He (Helen) Pu (b) (4) (b) (4)	09 Apr 2021 20:55:42



US3732304

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:26:54

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:23:22
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
User entered 'cta pulmonary embolus'	(b) (4) He (Helen) Pu (b) (4) (b) (4)	09 Apr 2021 20:55:42

**US3732304**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:23:22
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) He (Helen) Pu (b) (4) (b) (4)	09 Apr 2021 20:55:42

US3732304

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:26:54

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:41:15
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:23:22
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
User entered empty.	(b) (4) He (Helen) Pu (b) (4) (b) (4)	09 Apr 2021 20:55:42

US3732304

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:26:54

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:41:18
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:23:26
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
User entered '30 Oct 2020'	(b) (4) He (Helen) Pu (b) (4) (b) (4)	09 Apr 2021 20:55:59

**US3732304**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 10 Jun 2021 09:26:54**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:41:18
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:23:26
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
User entered 'bilateral venous duplex lower extremity ultrasound'	(b) (4) He (Helen) Pu (b) (4)	09 Apr 2021 20:55:59

**US3732304**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 10 Jun 2021 09:26:54**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:41:18
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:23:26
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) He (Helen) Pu (b) (4) (b) (4)	09 Apr 2021 20:55:59

US3732304

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:26:54

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:41:18
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:23:26
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
User entered empty.	(b) (4) He (Helen) Pu (b) (4) (b) (4)	09 Apr 2021 20:55:59

**US3732304**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (4)**

**Generated On: 10 Jun 2021 09:26:54**

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:41:21
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:23:26
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
User entered '02 Nov 2020'	(b) (4) He (Helen) Pu (b) (4) (b) (4)	09 Apr 2021 20:56:09



US3732304

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:26:54

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:41:21
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:23:26
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
User entered 'chest x-ray'	(b) (4) He (Helen) Pu (b) (4) (b) (4)	09 Apr 2021 20:56:09

**US3732304**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (4)**

**Generated On: 10 Jun 2021 09:26:54**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:41:21
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:23:26
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) He (Helen) Pu (b) (4) (b) (4)	09 Apr 2021 20:56:09

US3732304

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:26:54

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:41:21
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:23:26
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:41:43
User entered empty.	(b) (4) He (Helen) Pu (b) (4) (b) (4)	09 Apr 2021 20:56:09

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'USA-US102-2020-MRNA-1273-P301000004'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'Yes (Y)'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'No (N)'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'No (N)'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'Yes (Y)'	System	04 Nov 2020 16:37:53



**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'No (N)'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'No (N)'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'No (N)'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'Scott'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'Overcash'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered '5565 Grossmont Center Dr'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'La Mesa'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'CA'	System	04 Nov 2020 16:37:53



**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered '91942'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
Reviewed for Safety.	(b) (4)	25 Nov 2020 19:18:28
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:15:51
User entered 'US'	System	04 Nov 2020 16:39:02

US3732304

Folder: SAE USA-US102-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:54

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	26 Apr 2021 16:49:43
User entered '7'	System	21 Apr 2021 17:34:49
User entered '6'	System	20 Apr 2021 13:57:22
User entered '5'	System	16 Apr 2021 12:55:16
User entered '4'	System	12 Apr 2021 13:28:32
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
	(b) (4)	
User entered '3'	System	17 Feb 2021 16:11:54
User entered '2'	System	25 Nov 2020 19:18:41
User entered '1'	System	04 Nov 2020 16:39:02

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'USA-US102-2020-MRNA-1273-P301000004'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'Yes (Y)'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'No (N)'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'No (N)'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'Yes (Y)'	System	04 Nov 2020 16:37:53



**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'No (N)'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'No (N)'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'No (N)'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'Scott'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'Overcash'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered '5565 Grossmont Center Dr'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'La Mesa'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'CA'	System	04 Nov 2020 16:37:53



**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered '91942'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
Reviewed for Safety.	(b) (4)	25 Nov 2020 19:18:28
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:15:51
User entered 'US'	System	04 Nov 2020 16:39:02

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	26 Apr 2021 16:49:43
User entered '7'	System	21 Apr 2021 17:34:49
User entered '6'	System	20 Apr 2021 13:57:22
User entered '5'	System	16 Apr 2021 12:55:16
User entered '4'	System	12 Apr 2021 13:28:32
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
	(b) (4)	
User entered '3'	System	17 Feb 2021 16:11:54
User entered '2'	System	25 Nov 2020 19:18:41
User entered '1'	System	04 Nov 2020 16:39:02

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 09:26:54**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
User entered '04/Nov/2020 16:38'	System	04 Nov 2020 16:39:02

US3732304

Folder: SAE USA-US102-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:26:54

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
Reviewed for Safety.	(b) (4)	25 Nov 2020 19:18:28
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:15:51
User entered 'I'		04 Nov 2020 16:39:02

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'USA-US102-2020-MRNA-1273-P301000004'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'Yes (Y)'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'No (N)'	System	04 Nov 2020 16:37:53



**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'No (N)'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'Yes (Y)'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'No (N)'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'No (N)'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'No (N)'	System	04 Nov 2020 16:37:53

US3732304

Folder: SAE USA-US102-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:54

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'Scott'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'Overcash'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered '5565 Grossmont Center Dr'	System	04 Nov 2020 16:37:53



**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'La Mesa'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'CA'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered '91942'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 19:18:28
DataPoint Verified.		06 Nov 2020 22:15:51
User entered 'US'	System	04 Nov 2020 16:39:02

US3732304

Folder: SAE USA-US102-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:54

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	26 Apr 2021 16:49:43
User entered '7'	System	21 Apr 2021 17:34:49
User entered '6'	System	20 Apr 2021 13:57:22
User entered '5'	System	16 Apr 2021 12:55:16
User entered '4'	System	12 Apr 2021 13:28:32
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
	(b) (4)	
User entered '3'	System	17 Feb 2021 16:11:54
User entered '2'	System	25 Nov 2020 19:18:41
User entered '1'	System	04 Nov 2020 16:39:02

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 09:26:54**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 23:35:07
User entered '25/Nov/2020 14:18'	System	25 Nov 2020 19:18:41

US3732304

Folder: SAE USA-US102-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:26:54

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
Reviewed for Safety.	(b) (4)	17 Feb 2021 16:11:17
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 23:35:07
User entered 'I'		25 Nov 2020 19:18:41

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'USA-US102-2020-MRNA-1273-P301000004'	System	04 Nov 2020 16:37:53



**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'Yes (Y)'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'No (N)'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'No (N)'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'Yes (Y)'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'No (N)'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'No (N)'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'No (N)'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'Scott'	System	04 Nov 2020 16:37:53



**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'Overcash'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered '5565 Grossmont Center Dr'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'La Mesa'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'CA'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered '91942'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
Reviewed for Safety.	(b) (4)	25 Nov 2020 19:18:28
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:15:51
User entered 'US'	System	04 Nov 2020 16:39:02

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	26 Apr 2021 16:49:43
User entered '7'	System	21 Apr 2021 17:34:49
User entered '6'	System	20 Apr 2021 13:57:22
User entered '5'	System	16 Apr 2021 12:55:16
User entered '4'	System	12 Apr 2021 13:28:32
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
	(b) (4)	
User entered '3'	System	17 Feb 2021 16:11:54
User entered '2'	System	25 Nov 2020 19:18:41
User entered '1'	System	04 Nov 2020 16:39:02

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form (3)**

**Generated On: 10 Jun 2021 09:26:54**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 21:14:11
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered '17/Feb/2021 11:11'	(b) (4) System	17 Feb 2021 16:11:54



US3732304

Folder: SAE USA-US102-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:26:54

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 13:28:23
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 21:14:11
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
User entered 'I'	(b) (4), (b) (6)	17 Feb 2021 16:11:54

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'USA-US102-2020-MRNA-1273-P301000004'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'Yes (Y)'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'No (N)'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'No (N)'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'Yes (Y)'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'No (N)'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'No (N)'	System	04 Nov 2020 16:37:53



**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'No (N)'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'Scott'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'Overcash'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered '5565 Grossmont Center Dr'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'La Mesa'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'CA'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered '91942'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
Reviewed for Safety.	(b) (4)	25 Nov 2020 19:18:28
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:15:51
User entered 'US'	System	04 Nov 2020 16:39:02



US3732304

Folder: SAE USA-US102-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:54

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	26 Apr 2021 16:49:43
User entered '7'	System	21 Apr 2021 17:34:49
User entered '6'	System	20 Apr 2021 13:57:22
User entered '5'	System	16 Apr 2021 12:55:16
User entered '4'	System	12 Apr 2021 13:28:32
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
	(b) (4)	
User entered '3'	System	17 Feb 2021 16:11:54
User entered '2'	System	25 Nov 2020 19:18:41
User entered '1'	System	04 Nov 2020 16:39:02

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form (4)**

**Generated On: 10 Jun 2021 09:26:54**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:23:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:29:25
User entered '12/Apr/2021 09:28'	System	12 Apr 2021 13:28:32

US3732304

Folder: SAE USA-US102-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:26:54

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:23:32
Reviewed for Safety.	(b) (4)	21 Apr 2021 17:34:32
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:29:25
User entered 'I'		12 Apr 2021 13:28:32

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'USA-US102-2020-MRNA-1273-P301000004'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'Yes (Y)'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'No (N)'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'No (N)'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'Yes (Y)'	System	04 Nov 2020 16:37:53



**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'No (N)'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'No (N)'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'No (N)'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'Scott'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'Overcash'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered '5565 Grossmont Center Dr'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'La Mesa'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'CA'	System	04 Nov 2020 16:37:53



**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered '91942'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
Reviewed for Safety.	(b) (4)	25 Nov 2020 19:18:28
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:15:51
User entered 'US'	System	04 Nov 2020 16:39:02

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	26 Apr 2021 16:49:43
User entered '7'	System	21 Apr 2021 17:34:49
User entered '6'	System	20 Apr 2021 13:57:22
User entered '5'	System	16 Apr 2021 12:55:16
User entered '4'	System	12 Apr 2021 13:28:32
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
	(b) (4)	
User entered '3'	System	17 Feb 2021 16:11:54
User entered '2'	System	25 Nov 2020 19:18:41
User entered '1'	System	04 Nov 2020 16:39:02

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form (5)**

**Generated On: 10 Jun 2021 09:26:54**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:23:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 04:42:05
User entered '16/Apr/2021 05:55'	System	16 Apr 2021 12:55:16

US3732304

Folder: SAE USA-US102-2020-MRNA-1273-P301000004

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:26:54

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:23:32
Reviewed for Safety.	(b) (4)	21 Apr 2021 17:34:32
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 04:42:05
User entered '1'		16 Apr 2021 12:55:16

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'USA-US102-2020-MRNA-1273-P301000004'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'Yes (Y)'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'No (N)'	System	04 Nov 2020 16:37:53



**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'No (N)'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'Yes (Y)'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'No (N)'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'No (N)'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'No (N)'	System	04 Nov 2020 16:37:53

US3732304

Folder: SAE USA-US102-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:26:54

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'Scott'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'Overcash'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered '5565 Grossmont Center Dr'	System	04 Nov 2020 16:37:53



**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'La Mesa'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'CA'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered '91942'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
Reviewed for Safety.	(b) (4)	25 Nov 2020 19:18:28
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:15:51
User entered 'US'	System	04 Nov 2020 16:39:02

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	26 Apr 2021 16:49:43
User entered '7'	System	21 Apr 2021 17:34:49
User entered '6'	System	20 Apr 2021 13:57:22
User entered '5'	System	16 Apr 2021 12:55:16
User entered '4'	System	12 Apr 2021 13:28:32
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
	(b) (4)	
User entered '3'	System	17 Feb 2021 16:11:54
User entered '2'	System	25 Nov 2020 19:18:41
User entered '1'	System	04 Nov 2020 16:39:02

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form (6)**

**Generated On: 10 Jun 2021 09:26:54**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:23:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:09:28
User entered '20/Apr/2021 06:57'	System	20 Apr 2021 13:57:22

US3732304

Folder: SAE USA-US102-2020-MRNA-1273-P301000004

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:26:54

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:23:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 18:09:28
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 17:34:32
User entered 'I'	(b) (4), (b) (6)	20 Apr 2021 13:57:22

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'USA-US102-2020-MRNA-1273-P301000004'	System	04 Nov 2020 16:37:53



**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'Yes (Y)'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'No (N)'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'No (N)'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'Yes (Y)'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'No (N)'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'No (N)'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'No (N)'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'Scott'	System	04 Nov 2020 16:37:53



**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'Overcash'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered '5565 Grossmont Center Dr'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'La Mesa'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'CA'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered '91942'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
Reviewed for Safety.	(b) (4)	25 Nov 2020 19:18:28
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:15:51
User entered 'US'	System	04 Nov 2020 16:39:02

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	26 Apr 2021 16:49:43
User entered '7'	System	21 Apr 2021 17:34:49
User entered '6'	System	20 Apr 2021 13:57:22
User entered '5'	System	16 Apr 2021 12:55:16
User entered '4'	System	12 Apr 2021 13:28:32
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
	(b) (4)	
User entered '3'	System	17 Feb 2021 16:11:54
User entered '2'	System	25 Nov 2020 19:18:41
User entered '1'	System	04 Nov 2020 16:39:02

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form (7)**

**Generated On: 10 Jun 2021 09:26:54**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:23:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:09:28
User entered '21/Apr/2021 13:34'	System	21 Apr 2021 17:34:49



US3732304

Folder: SAE USA-US102-2020-MRNA-1273-P301000004

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 09:26:54

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:23:32
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	26 Apr 2021 16:49:32
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 18:09:28
User entered 'I'	(b) (4), (b) (6)	21 Apr 2021 17:34:49

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'USA-US102-2020-MRNA-1273-P301000004'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'Yes (Y)'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'No (N)'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'No (N)'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'Yes (Y)'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'No (N)'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'No (N)'	System	04 Nov 2020 16:37:53



**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'No (N)'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'Scott'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'Overcash'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered '5565 Grossmont Center Dr'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'La Mesa'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered 'CA'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:15:51
Reviewed for Safety.	(b) (4), (b) (6)	04 Nov 2020 16:38:49
User entered '91942'	System	04 Nov 2020 16:37:53

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
Reviewed for Safety.	(b) (4)	25 Nov 2020 19:18:28
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:15:51
User entered 'US'	System	04 Nov 2020 16:39:02



**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:26:54**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	26 Apr 2021 16:49:43
User entered '7'	System	21 Apr 2021 17:34:49
User entered '6'	System	20 Apr 2021 13:57:22
User entered '5'	System	16 Apr 2021 12:55:16
User entered '4'	System	12 Apr 2021 13:28:32
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:40:39
	(b) (4)	
User entered '3'	System	17 Feb 2021 16:11:54
User entered '2'	System	25 Nov 2020 19:18:41
User entered '1'	System	04 Nov 2020 16:39:02

**US3732304**

**Folder: SAE USA-US102-2020-MRNA-1273-P301000004**

**Form: Safety Report Form (8)**

**Generated On: 10 Jun 2021 09:26:54**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:23:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 21:30:36
User entered '26/Apr/2021 12:49'	System	26 Apr 2021 16:49:43

US3732304

Folder: SAE USA-US102-2020-MRNA-1273-P301000004

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 09:26:54

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:23:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Apr 2021 21:30:36
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 16:51:17
User entered 'I'	(b) (4), (b) (6)	26 Apr 2021 16:49:43