

US3732023 (Prod: eStudySite - La Mesa - PPDS)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:28:58

All time stamps listed in this document are displayed in GMT

US3732023

Form: Participant Creation

Data signed: (b) (4) 13 Feb 2021 01:31:47

Generated On: 10 Jun 2021 09:28:58

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Participant ID

US3732023

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

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US3732023

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 24 Feb 2021 21:52:16

Generated On: 10 Jun 2021 09:28:58

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	07 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3732023

Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 01:31:48

Generated On: 10 Jun 2021 09:28:58

Date of Birth (MMM yyyy)	(b) (6) 1948
Age	71
Age Units	YEARS
Age (Derived)	71
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 01:31:48

Generated On: 10 Jun 2021 09:28:58

Date of Informed Consent ( <i>dd MMM yyyy</i> )	07 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input checked="" type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3732023

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 01:31:48

Generated On: 10 Jun 2021 09:28:58

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Did the participant meet all eligibility criteria?

Yes ☒  
No ☐

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US3732023

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 24 Feb 2021 21:52:09

Generated On: 10 Jun 2021 09:28:58

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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) 28 Apr 2021 22:19:26

Generated On: 10 Jun 2021 09:28:58

Condition	LATEX ALLERGY
Start date (dd MMM yyyy)	UN UNK 1980
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 1980
Start Year (derived)	1980
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 28 Apr 2021 22:19:26

Generated On: 10 Jun 2021 09:28:58

Condition	GEL CAPSULE ALLERGY
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 28 Apr 2021 22:19:26

Generated On: 10 Jun 2021 09:28:58

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

US3732023

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 28 Apr 2021 22:19:26

Generated On: 10 Jun 2021 09:28:58

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 28 Apr 2021 22:19:26

Generated On: 10 Jun 2021 09:28:58

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

US3732023

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 28 Apr 2021 22:19:26

Generated On: 10 Jun 2021 09:28:58

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 28 Apr 2021 22:19:26

Generated On: 10 Jun 2021 09:28:58

Condition	WINE ALLERGY
Start date (dd MMM yyyy)	UN UNK 1980
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 1980
Start Year (derived)	1980
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 28 Apr 2021 22:19:26

Generated On: 10 Jun 2021 09:28:58

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

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 28 Apr 2021 22:19:26

Generated On: 10 Jun 2021 09:28:58

Condition	POSITIVE TUBERCULOSIS TEST
Start date (dd MMM yyyy)	UN UNK 1960
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1960
Start Year (derived)	1960
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 28 Apr 2021 22:19:26

Generated On: 10 Jun 2021 09:28:58

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

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 28 Apr 2021 22:19:26

Generated On: 10 Jun 2021 09:28:58

Condition	MYOPIA - BILATERAL
Start date (dd MMM yyyy)	UN UNK 1960
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1960
Start Year (derived)	1960
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 28 Apr 2021 22:19:26

Generated On: 10 Jun 2021 09:28:58

Condition	BILATERAL OSTEOARTHRITIS IN KNEES
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2019
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	JAN 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 28 Apr 2021 22:19:26

Generated On: 10 Jun 2021 09:28:58

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

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 28 Apr 2021 22:19:26

Generated On: 10 Jun 2021 09:28:58

Condition	LYME DISEASE
Start date (dd MMM yyyy)	UN UNK 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)	UN UNK 2015
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 28 Apr 2021 22:19:26

Generated On: 10 Jun 2021 09:28:58

Condition	HYSTERECTOMY
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1990
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	JAN 1990
Stop Year (derived)	1990

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 28 Apr 2021 22:19:26

Generated On: 10 Jun 2021 09:28:58

Condition	MENOPAUSE
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1990
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	JAN 1990
Stop Year (derived)	1990

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 28 Apr 2021 22:19:26

Generated On: 10 Jun 2021 09:28:58

Condition	ALCOHOL USE
Start date (dd MMM yyyy)	UN UNK 1969
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 1969
Start Year (derived)	1969
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 28 Apr 2021 22:19:26

Generated On: 10 Jun 2021 09:28:58

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

US3732023

Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 28 Apr 2021 22:19:26

Generated On: 10 Jun 2021 09:28:58

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

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Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 28 Apr 2021 22:19:26

Generated On: 10 Jun 2021 09:28:58

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

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Folder: Screening

Form: Medical History (21)

Data signed: (b) (4) 28 Apr 2021 22:19:26

Generated On: 10 Jun 2021 09:28:58

Condition	CONSTIPATION
Start date (dd MMM yyyy)	UN UNK 1970
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1970
Start Year (derived)	1970
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3732023

Folder: Screening

Form: Medical History (22)

Data signed: (b) (4) 28 Apr 2021 22:19:26

Generated On: 10 Jun 2021 09:28:58

Condition	POST-MENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

US3732023

Folder: Screening

Form: Medical History (23)

Data signed: (b) (4) 28 Apr 2021 22:19:26

Generated On: 10 Jun 2021 09:28:58

Condition	BILATERAL KNEE REPLACEMENT
Start date (dd MMM yyyy)	UN AUG 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN AUG 2019
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2019
Start Year (derived)	2019
Stop Month and Year (derived)	AUG 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (24)

Data signed: (b) (4) 28 Apr 2021 22:19:26

Generated On: 10 Jun 2021 09:28:58

Condition	GENERAL ARTHRITIS
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

US3732023

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 24 Feb 2021 21:52:18

Generated On: 10 Jun 2021 09:28:58

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	07 AUG 2020
Time of assessment (00:00-23:59)	11:25 (24 HR)
Vital Signs Date and Time (derived)	07 AUG 2020 11:25
Height (xxx.x)	158.3 cm
Weight (xxx.x)	69.8 kg
BMI (xxx.x)	27.85439 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3732023

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 24 Feb 2021 21:52:09

Generated On: 10 Jun 2021 09:28:58

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

07 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 13 Feb 2021 01:31:48

Generated On: 10 Jun 2021 09:28:58

Date of assessment (*dd MMM yyyy*) 07 AUG 2020

Is the participant of childbearing potential? Yes ☐  
No ☒

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

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

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

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) UN UNK 1990

Date of last menstruation unknown False

US3732023

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 24 Feb 2021 21:52:11

Generated On: 10 Jun 2021 09:28:58

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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) 24 Feb 2021 21:52:11

Generated On: 10 Jun 2021 09:28:58

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 24 Feb 2021 21:52:30

Generated On: 10 Jun 2021 09:28:58

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	07 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 24 Feb 2021 21:52:28

Generated On: 10 Jun 2021 09:28:58

What was the date of randomization? (dd MMM yyyy) 07 AUG 2020

What was the participant's randomization number? 185237

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 24 Feb 2021 21:52:32

Generated On: 10 Jun 2021 09:28:58

Height	ND - Not Done
Weight	ND - Not Done

US3732023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 24 Feb 2021 21:52:32

Generated On: 10 Jun 2021 09:28:58

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)	07 AUG 2020
Time of assessment (00:00-23:59)	11:25 (24 HR)
Vital Signs Date and Time (derived)	07 AUG 2020 11:25
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)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 24 Feb 2021 21:52:32

Generated On: 10 Jun 2021 09:28:58

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)	07 AUG 2020
Time of assessment (00:00-23:59)	12:36 (24 HR)
Vital Signs Date and Time (derived)	07 AUG 2020 12:36
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)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	96 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 24 Feb 2021 21:52:27

Generated On: 10 Jun 2021 09:28:58

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 24 Feb 2021 21:52:23

Generated On: 10 Jun 2021 09:28:58

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 AUG 2020

What was the treatment time? (00:00-23:59) 12:06 (24 HR)

Treatment Date and Time (derived) 07 AUG 2020 12:06

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

US3732023

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Feb 2021 21:52:25

Generated On: 10 Jun 2021 09:28:58

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	07 AUG 2020
Collection time (00:00-23:59)	11:46 (24 HR)
Collection date and time (derived)	07 AUG 2020 11:46

US3732023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 24 Feb 2021 21:52:21

Generated On: 10 Jun 2021 09:28:58

Collection date (dd MMM yyyy)			07 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:43	07 AUG 2020 11:43
Nasopharyngeal Swab 2	No		

US3732023

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 21:52:23

Generated On: 10 Jun 2021 09:28:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 AUG 2020 12:46

PC Open Date & Time

07 AUG 2020 12:26

PC Close Date & Time

07 AUG 2020 14:56

US3732023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:28:58

**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

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 07 AUG 2020 15:51

PC Close Date & Time 08 AUG 2020 11:59



US3732023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

08 AUG 2020 19:46

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3732023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:28:58

**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

98.4 °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 AUG 2020 20:00

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3732023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:28:58

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**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 AUG 2020 23:50

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3732023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 AUG 2020 22:41

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3732023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

12 AUG 2020 22:53

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3732023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:28:58

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 22:15

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

07 AUG 2020 12:47

PC Open Date & Time

07 AUG 2020 12:26

PC Close Date & Time

07 AUG 2020 14:56

US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:28:58

**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

07 AUG 2020 15:51

PC Close Date & Time

08 AUG 2020 11:59



US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:28:58

**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 AUG 2020 19:47

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:28:58

**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

09 AUG 2020 20:02

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:28:58

**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 AUG 2020 23:50

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:28:58

**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

11 AUG 2020 22:41

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:28:58

**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

12 AUG 2020 22:53

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:28:58

**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 AUG 2020 22:16

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:58

**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 ☐

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:58

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

No ☒

Yes ☐

PC Time stamp	07 AUG 2020 12:48
PC Open Date & Time	07 AUG 2020 12:26
PC Close Date & Time	07 AUG 2020 14:56



US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:58

**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 ☐

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:58

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

07 AUG 2020 15:51

PC Close Date & Time

08 AUG 2020 11:59

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:58

**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 ☒

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:58

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 19:49
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:58

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 ☒

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:58

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 20:04
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:58

**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 ☒

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:58

Yes <input type="checkbox"/>	
PC Time stamp	10 AUG 2020 23:51
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59



US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

DAY 5

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:58

Yes <input type="checkbox"/>	
PC Time stamp	11 AUG 2020 22:42
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

DAY 6

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:58

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 22:53
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:58

**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 ☒

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:58

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 22:16
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3732023

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:31:48

Generated On: 10 Jun 2021 09:28:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3732023

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:31:48

Generated On: 10 Jun 2021 09:28:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3732023

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:31:48

Generated On: 10 Jun 2021 09:28:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3732023

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:31:48

Generated On: 10 Jun 2021 09:28:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732023

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:31:48

Generated On: 10 Jun 2021 09:28:58

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3732023

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:31:48

Generated On: 10 Jun 2021 09:28:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732023

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 24 Feb 2021 21:52:51

Generated On: 10 Jun 2021 09:28:58

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3732023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 24 Feb 2021 21:52:53

Generated On: 10 Jun 2021 09:28:58

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	04 SEP 2020
Time of assessment (00:00-23:59)	10:40 (24 HR)
Vital Signs Date and Time (derived)	04 SEP 2020 10:40
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)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	91 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	59 mmHg
Diastolic Blood Pressure units	MMHG

US3732023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 24 Feb 2021 21:52:53

Generated On: 10 Jun 2021 09:28:58

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)	04 SEP 2020
Time of assessment (00:00-23:59)	11:55 (24 HR)
Vital Signs Date and Time (derived)	04 SEP 2020 11:55
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	57 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	101 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

US3732023

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Feb 2021 21:52:50

Generated On: 10 Jun 2021 09:28:58

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

04 SEP 2020

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



US3732023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 24 Feb 2021 21:52:47

Generated On: 10 Jun 2021 09:28:58

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) 04 SEP 2020

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

Treatment Date and Time (derived) 04 SEP 2020 11:25

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

What was the frequency of the study treatment dosing? ONCE

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

US3732023

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Feb 2021 21:52:49

Generated On: 10 Jun 2021 09:28:58

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	04 SEP 2020
Collection time (00:00-23:59)	11:03 (24 HR)
Collection date and time (derived)	04 SEP 2020 11:03

US3732023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 24 Feb 2021 21:52:42

Generated On: 10 Jun 2021 09:28:58

Collection date (dd MMM yyyy)			04 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:43	04 SEP 2020 10:43
Nasopharyngeal Swab 2	No		

US3732023

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 21:52:46

Generated On: 10 Jun 2021 09:28:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 12:01

PC Open Date & Time

04 SEP 2020 11:45

PC Close Date & Time

04 SEP 2020 14:15

US3732023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:28:58

**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

04 SEP 2020 21:20

PC Open Date & Time

04 SEP 2020 15:10

PC Close Date & Time

05 SEP 2020 11:59

US3732023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:28:58

**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

99.9 °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

05 SEP 2020 21:41

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3732023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:28:58

**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

98.6 °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

06 SEP 2020 19:49

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59



US3732023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:28:58

**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

98.2 °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

07 SEP 2020 21:56

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3732023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

09 SEP 2020 00:04

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3732023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

09 SEP 2020 21:55

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3732023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:28:58

**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

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 20:00

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:28:58

**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

04 SEP 2020 12:01

PC Open Date & Time

04 SEP 2020 11:45

PC Close Date & Time

04 SEP 2020 14:15

US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:28:58

**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

04 SEP 2020 21:20

PC Open Date & Time

04 SEP 2020 15:10

PC Close Date & Time

05 SEP 2020 11:59

US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:28:58

**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

05 SEP 2020 21:42

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:28:58

**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

06 SEP 2020 19:50

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59



US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:28:58

**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

07 SEP 2020 21:56

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:28:58

**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

09 SEP 2020 00:05

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:28:58

**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

09 SEP 2020 21:56

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:28:58

**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

10 SEP 2020 20:01

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:58

**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 ☐

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:58

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

No ☒

Yes ☐

PC Time stamp	04 SEP 2020 12:02
PC Open Date & Time	04 SEP 2020 11:45
PC Close Date & Time	04 SEP 2020 14:15

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:58

**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 ☐

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:58

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

No ☒

Yes ☐

PC Time stamp	04 SEP 2020 21:21
PC Open Date & Time	04 SEP 2020 15:10
PC Close Date & Time	05 SEP 2020 11:59



US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:58

**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 ☒

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:58

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 21:45
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:58

**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 ☒

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:58

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 19:51
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:58

**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 ☒

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:58

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 21:56
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:58

**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 ☒

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:58

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 00:05
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59



US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:58

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

120 of 2341

EAB) (1725)

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:58

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 21:56
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:58

**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)

122 of 2341

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:58

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 20:01
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3732023

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:31:48

Generated On: 10 Jun 2021 09:28:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3732023

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:31:48

Generated On: 10 Jun 2021 09:28:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732023

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:31:48

Generated On: 10 Jun 2021 09:28:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3732023

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:31:48

Generated On: 10 Jun 2021 09:28:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3732023

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:31:48

Generated On: 10 Jun 2021 09:28:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3732023

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:31:48

Generated On: 10 Jun 2021 09:28:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732023

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 24 Feb 2021 21:53:02

Generated On: 10 Jun 2021 09:28:58

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3732023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 24 Feb 2021 21:53:03

Generated On: 10 Jun 2021 09:28:58

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	02 OCT 2020
Time of assessment (00:00-23:59)	11:10 (24 HR)
Vital Signs Date and Time (derived)	02 OCT 2020 11:10
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	109 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	60 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3732023

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Feb 2021 21:53:01

Generated On: 10 Jun 2021 09:28:58

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 OCT 2020

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

US3732023

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Feb 2021 21:53:00

Generated On: 10 Jun 2021 09:28:58

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	02 OCT 2020
Collection time (00:00-23:59)	11:27 (24 HR)
Collection date and time (derived)	02 OCT 2020 11:27

US3732023

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 21:52:59

Generated On: 10 Jun 2021 09:28:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

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 checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	07 OCT 2020 19:42:49
Patient Cloud Open Date & Time	07 OCT 2020 00:01
Patient Cloud Close Date & Time	11 OCT 2020 23:59



US3732023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 OCT 2020 13:52:43

Patient Cloud Open Date & Time

14 OCT 2020 00:01

Patient Cloud Close Date & Time

18 OCT 2020 23:59

US3732023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 OCT 2020 21:25:58

Patient Cloud Open Date & Time

21 OCT 2020 00:01

Patient Cloud Close Date & Time

25 OCT 2020 23:59

US3732023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 NOV 2020 07:14:01

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3732023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 NOV 2020 20:27:40
Patient Cloud Open Date & Time	11 NOV 2020 00:01
Patient Cloud Close Date & Time	15 NOV 2020 23:59

US3732023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

DAY 106

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 NOV 2020 06:49:15

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

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"/>

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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

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[Patient Cloud Open Date & Time](#)

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22 NOV 2020 00:01

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[Patient Cloud Close Date & Time](#)

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26 NOV 2020 23:59

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US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**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

29 NOV 2020 07:15:03

Patient Cloud Open Date & Time

29 NOV 2020 00:01

Patient Cloud Close Date & Time

03 DEC 2020 23:59



US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 DEC 2020 22:09:31
Patient Cloud Open Date & Time	06 DEC 2020 00:01
Patient Cloud Close Date & Time	10 DEC 2020 23:59

US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 DEC 2020 06:34:00

Patient Cloud Open Date & Time

13 DEC 2020 00:01

Patient Cloud Close Date & Time

17 DEC 2020 23:59

US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**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

20 DEC 2020 20:57:46

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

<b>TIMEPOINT</b>	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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 DEC 2020 22:21:29
Patient Cloud Open Date & Time	27 DEC 2020 00:01
Patient Cloud Close Date & Time	31 DEC 2020 23:59

US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**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

03 JAN 2021 00:02:21

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**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

10 JAN 2021 15:33:12

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**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

17 JAN 2021 12:05:26

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 JAN 2021 14:14:02

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59



US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	31 JAN 2021 08:39:56
Patient Cloud Open Date & Time	31 JAN 2021 00:01
Patient Cloud Close Date & Time	04 FEB 2021 23:59

US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**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

07 FEB 2021 09:32:25

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59

US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 FEB 2021 06:46:59
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 FEB 2021 08:04:35
Patient Cloud Open Date & Time	21 FEB 2021 00:01
Patient Cloud Close Date & Time	25 FEB 2021 23:59

US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 FEB 2021 13:57:27

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**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

07 MAR 2021 09:06:57

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**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

14 MAR 2021 09:25:35

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 MAR 2021 05:39:07

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59



US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**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

28 MAR 2021 12:13:43

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 APR 2021 08:45:13

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 APR 2021 11:16:23

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 APR 2021 10:17:05

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	25 APR 2021 10:07:37
Patient Cloud Open Date & Time	25 APR 2021 00:01
Patient Cloud Close Date & Time	29 APR 2021 23:59

US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAY 2021 09:33:54

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

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

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

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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

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[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

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US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

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

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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

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[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

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US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

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

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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

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[Patient Cloud Close Date & Time](#)

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27 MAY 2021 23:59

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US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**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 ☐

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

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="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"/>

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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

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[Patient Cloud Open Date & Time](#)

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06 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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10 JUN 2021 23:59

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US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

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

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

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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

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[Patient Cloud Open Date & Time](#)

13 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

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US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

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

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	20 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 JUN 2021 23:59

US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

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

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

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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

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[Patient Cloud Close Date & Time](#)

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01 JUL 2021 23:59

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US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

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

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	04 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	08 JUL 2021 23:59



US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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

US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

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"/>

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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

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[Patient Cloud Close Date & Time](#)

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22 JUL 2021 23:59

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US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

DAY 355

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

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

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

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

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

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

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

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

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	25 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 JUL 2021 23:59

US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

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

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

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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

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[Patient Cloud Open Date & Time](#)

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01 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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05 AUG 2021 23:59

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US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**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 ☐

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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

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[Patient Cloud Close Date & Time](#)

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12 AUG 2021 23:59

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US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**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 ☐

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	15 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	19 AUG 2021 23:59
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US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**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 ☐

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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

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[Patient Cloud Open Date & Time](#)

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22 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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26 AUG 2021 23:59

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US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

DAY 390

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59



US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**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 ☐

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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

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[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

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US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

DAY 404

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

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

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

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

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

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

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

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

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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

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[Patient Cloud Open Date & Time](#)

12 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

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US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

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"/>

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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

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[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

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US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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



US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

DAY 425

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

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

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

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

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

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

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

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

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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

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[Patient Cloud Open Date & Time](#)

03 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

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US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**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 ☐

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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

US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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

US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**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 ☐ Yes ☐

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

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59



US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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

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[Patient Cloud Close Date & Time](#)

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04 NOV 2021 23:59

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US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

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"/>

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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

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[Patient Cloud Close Date & Time](#)

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11 NOV 2021 23:59

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US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

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

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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

US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**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 ☐

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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

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[Patient Cloud Open Date & Time](#)

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21 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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25 NOV 2021 23:59

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US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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

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[Patient Cloud Open Date & Time](#)

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28 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 DEC 2021 23:59

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US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

DAY 488

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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

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[Patient Cloud Close Date & Time](#)

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09 DEC 2021 23:59

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US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

DAY 495

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

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

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

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

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

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

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

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

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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

US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**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 ☐

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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



US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

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

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

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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

US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**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 ☐

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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

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[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

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US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

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"/>

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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

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[Patient Cloud Open Date & Time](#)

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16 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 JAN 2022 23:59

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US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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

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[Patient Cloud Open Date & Time](#)

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23 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 JAN 2022 23:59

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US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

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

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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

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[Patient Cloud Close Date & Time](#)

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03 FEB 2022 23:59

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US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**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 ☐

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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

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[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

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US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**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 ☐

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	13 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 FEB 2022 23:59



US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**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 ☐

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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

US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**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 ☐

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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

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[Patient Cloud Close Date & Time](#)

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03 MAR 2022 23:59

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US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**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 ☐

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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

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[Patient Cloud Open Date & Time](#)

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06 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 MAR 2022 23:59

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US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**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 ☐

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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

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[Patient Cloud Open Date & Time](#)

13 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

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US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**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 ☐

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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

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[Patient Cloud Close Date & Time](#)

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24 MAR 2022 23:59

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US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

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"/>

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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

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[Patient Cloud Close Date & Time](#)

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31 MAR 2022 23:59

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US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

TIMEPOINT

DAY 607

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

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

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

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

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

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

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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

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[Patient Cloud Open Date & Time](#)

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03 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 APR 2022 23:59

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US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 APR 2022 23:59



US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

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"/>

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

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

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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

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[Patient Cloud Open Date & Time](#)

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24 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 APR 2022 23:59

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US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

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 ☐

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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

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[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

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US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**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 ☐

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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

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[Patient Cloud Close Date & Time](#)

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12 MAY 2022 23:59

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US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**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°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 ☐

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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

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[Patient Cloud Open Date & Time](#)

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15 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 MAY 2022 23:59

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US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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

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[Patient Cloud Open Date & Time](#)

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22 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 MAY 2022 23:59

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US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**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 ☐

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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

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[Patient Cloud Close Date & Time](#)

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02 JUN 2022 23:59

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US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

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

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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

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[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

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US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**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 ☐

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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

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[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

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US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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

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[Patient Cloud Open Date & Time](#)

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19 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 JUN 2022 23:59

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US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**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 ☐  
Yes ☐

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

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

DAY 698

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

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

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

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

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

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

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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

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[Patient Cloud Close Date & Time](#)

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07 JUL 2022 23:59

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US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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

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[Patient Cloud Open Date & Time](#)

10 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

14 JUL 2022 23:59

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US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**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 ☐

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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

US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

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

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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

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[Patient Cloud Close Date & Time](#)

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28 JUL 2022 23:59

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US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

DAY 726

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

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

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

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

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

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

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

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

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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

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[Patient Cloud Close Date & Time](#)

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04 AUG 2022 23:59

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US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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

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[Patient Cloud Open Date & Time](#)

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07 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 AUG 2022 23:59

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US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

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

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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

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[Patient Cloud Open Date & Time](#)

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14 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 AUG 2022 23:59

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US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**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°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 ☐

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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

US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**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 ☐

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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

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[Patient Cloud Open Date & Time](#)

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28 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

---

01 SEP 2022 23:59

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US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

DAY 768

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

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

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

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

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

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

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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

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[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

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US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**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 ☐

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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

US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**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 ☐

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	25 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 SEP 2022 23:59



US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**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 ☐

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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

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[Patient Cloud Close Date & Time](#)

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06 OCT 2022 23:59

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US3732023

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

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"/>

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

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

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[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

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US3732023

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:28:58

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 13:57:37

US3732023

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:31:48

Generated On: 10 Jun 2021 09:28:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3732023

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:31:48

Generated On: 10 Jun 2021 09:28:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732023

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:31:48

Generated On: 10 Jun 2021 09:28:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3732023

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:31:48

Generated On: 10 Jun 2021 09:28:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732023

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:31:48

Generated On: 10 Jun 2021 09:28:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3732023

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:31:48

Generated On: 10 Jun 2021 09:28:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732023

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:31:48

Generated On: 10 Jun 2021 09:28:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3732023

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:31:48

Generated On: 10 Jun 2021 09:28:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732023

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 31 Mar 2021 22:55:22

Generated On: 10 Jun 2021 09:28:58

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3732023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 20:54:37

Generated On: 10 Jun 2021 09:28:58

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	15 MAR 2021
Time of assessment ( <i>00:00-23:59</i> )	08:45 (24 HR)
Vital Signs Date and Time (derived)	15 MAR 2021 08:45
Temperature ( <i>xxx.x</i> )	97.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	71 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	105 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	59 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3732023

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 31 Mar 2021 22:55:22

Generated On: 10 Jun 2021 09:28:58

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 MAR 2021

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



US3732023

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 31 Mar 2021 22:55:22

Generated On: 10 Jun 2021 09:28:58

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

15 MAR 2021

Collection time (00:00-23:59)

08:55 (24 HR)

Collection date and time (derived)

15 MAR 2021 08:55

US3732023

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 31 Mar 2021 22:55:22

Generated On: 10 Jun 2021 09:28:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732023

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 20:54:37

Generated On: 10 Jun 2021 09:28:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3732023

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 20:54:37

Generated On: 10 Jun 2021 09:28:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732023

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

03 MAY 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3732023

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:28:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3732023**

**Folder: Safety Call Day 299 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:28:58**

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*

**US3732023**

**Folder: Safety Call Day 299 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:28:58**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag



US3732023

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:28:58

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"/>

**US3732023**

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

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

**Generated On: 10 Jun 2021 09:28:58**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3732023

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

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 01:31:48

Generated On: 10 Jun 2021 09:28:58

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

Visit date (dd MMM yyyy)	26 JAN 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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US3732023

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

Form: Unblinding

Data signed: (b) (4) 31 Mar 2021 22:55:22

Generated On: 10 Jun 2021 09:28:58

Date of updated informed consent (dd MMM yyyy) 26 JAN 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (dd MMM yyyy) 26 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag \_\_\_\_\_  
Continuing with mRNA-1273 \_\_\_\_\_

US3732023

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 01:31:48

Generated On: 10 Jun 2021 09:28:58

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

26 JAN 2021

Collection time (00:00-23:59)

11:05 (24 HR)

Collection date and time (derived)

26 JAN 2021 11:05

US3732023

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 13 Feb 2021 01:31:48

Generated On: 10 Jun 2021 09:28:58

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	26 JAN 2021
Collection time (00:00 - 23:59)	10:52
Collection Date and Time (derived)	26 JAN 2021 10:52

US3732023

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 13 Feb 2021 01:31:47

Generated On: 10 Jun 2021 09:28:58

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Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3732023

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 22:19:25

Generated On: 10 Jun 2021 09:28:58

AEID

Adverse event

RIGHT EYE CATARACT

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)

06 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)

10 DEC 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

343 of 2341

EAB) (1725)



US3732023

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 22:19:25

Generated On: 10 Jun 2021 09:28:58

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

US3732023

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 22:19:25

Generated On: 10 Jun 2021 09:28:58

AEID

Adverse event

LEFT EYE CATARACT

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)

06 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)

25 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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US3732023

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 22:19:25

Generated On: 10 Jun 2021 09:28:58

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

US3732023

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 22:19:25

Generated On: 10 Jun 2021 09:28:58

AEID	
Adverse event	LEFT HIP PINCHED NERVE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	16 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

US3732023

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 22:19:25

Generated On: 10 Jun 2021 09:28:58

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

US3732023

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 22:19:25

Generated On: 10 Jun 2021 09:28:58

AEID	USA-US102-2021-MRNA-1273-P30 1000009
Adverse event	BROKEN HIP
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	22 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	23 APR 2021
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 22:19:25

Generated On: 10 Jun 2021 09:28:58

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 type="radio"/> Related <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Relationship to Study Procedure	Not Related <input type="radio"/> Related <input type="radio"/> Not Applicable <input checked="" 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	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input 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)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 13 Feb 2021 01:31:48

Generated On: 10 Jun 2021 09:28:58

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

Yes ☒

No ☐

---

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

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US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:28:58

Name of Medication	MELATONIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	INSOMNIA
Dose per administration	10
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:28:58

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:28:58

Name of Medication	FLONASE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	SEASONAL ALLERGIES
Dose per administration	50
Dose unit	mg <input type="radio"/> ug <input checked="" type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:28:58

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input checked="" type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:28:58

Name of Medication	SIMILASAN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	SEASONAL ALLERGIES
Dose per administration	1
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
If dose unit is Other, specify	DROP
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input checked="" type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:28:58

	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 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) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:28:58

Name of Medication	ASPIRIN
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	NON-MIGRAINE HEADACHES, AND BACK PAIN
Dose per administration	325
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input checked="" type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:28:58

	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 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)		_____
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 (5)

Generated On: 10 Jun 2021 09:28:58

Name of Medication	TYLENOL
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	NON-MIGRAINE HEADACHES AND BACK PAIN
Dose per administration	500
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input checked="" type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:28:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		UN UNK 2015
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		_____
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)

Generated On: 10 Jun 2021 09:28:58

Name of Medication	FLU VACCINE
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	INFLUENZA
Dose per administration	0.5
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input checked="" type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:28:58

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		05 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		05 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:28:58

Name of Medication	METHYL FOLATE
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	VITAMIN DEFICIENCY
Dose per administration	400
Dose unit	mg <input type="radio"/> ug <input checked="" type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:28:58

	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)		20 DEC 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)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:28:58

Name of Medication	MAGNESIUM
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	MAGNESIUM DEFICIENCY
Dose per administration	400
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:28:58

	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)		20 DEC 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)		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)

Generated On: 10 Jun 2021 09:28:58

Name of Medication	VITAMIN B6
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	VITAMIN DEFICIENCY
Dose per administration	25
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:28:58

	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)		20 DEC 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)		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)

Generated On: 10 Jun 2021 09:28:58

Name of Medication	VITAMIN B12
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	VITAMIN DEFICIENCY
Dose per administration	1000
Dose unit	mg <input type="radio"/> ug <input checked="" type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:28:58

	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)		20 DEC 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)		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)

Generated On: 10 Jun 2021 09:28:58

Name of Medication	OCUFLOX 0.3%
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	RIGHT EYE CATARACT SURGERY
Dose per administration	1
Dose unit	mg <input type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input checked="" type="checkbox"/>
If dose unit is Other, specify	DROP
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input checked="" type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:28:58

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		10 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 17 DEC 2020		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		4
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:28:58

Name of Medication	PREDNISONE ACETATE 1%
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	RIGHT EYE CATARACT SURGERY
Dose per administration	4
Dose unit	mg <input type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input checked="" type="checkbox"/>
If dose unit is Other, specify	DROP
Frequency	once daily <input checked="" type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:28:58

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		10 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		17 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:28:58

Name of Medication	PREDNISONE ACETATE 1%
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	RIGHT EYE CATARACT SURGERY
Dose per administration	2
Dose unit	mg <input type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input checked="" type="checkbox"/>
If dose unit is Other, specify	DROPS
Frequency	once daily <input checked="" type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:28:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		17 DEC 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)		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 (14)

Generated On: 10 Jun 2021 09:28:58

Name of Medication	PREDNISONE ACETATE 1%
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	LEFT EYE CATARACT SURGERY
Dose per administration	2
Dose unit	mg <input type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input checked="" type="checkbox"/>
If dose unit is Other, specify	DROPS
Frequency	once daily <input checked="" type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input checked="" type="checkbox"/>

PRODUCTION RELEASE (v12.003  
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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:28:58

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		25 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)		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 (15)

Generated On: 10 Jun 2021 09:28:58

Name of Medication	IBUPROFEN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	LEFT HIP PINCHED NERVE
Dose per administration	600
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:28:58

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		16 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		_____
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 (16)

Generated On: 10 Jun 2021 09:28:58

Name of Medication	BACLOFEN
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	LEFT HIP PINCHED NERVE
Dose per administration	5
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input checked="" type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:28:58

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		16 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		23 APR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>



US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:28:58

Name of Medication	NEURONTIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	LEFT HIP PINCHED NERVE
Dose per administration	300
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input checked="" type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:28:58

	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)		20 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		23 APR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 13 Feb 2021 01:31:48

Generated On: 10 Jun 2021 09:28:58

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 09 Apr 2021 20:54:37

Generated On: 10 Jun 2021 09:28:58

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
10 DEC 2020	RIGHT CATARACT SURGERY	Adverse Event	
25 FEB 2021	LEFT CATARACT SURGERY	Adverse Event	
01 MAR 2021	MAMMOGRAM	Diagnostic	
23 MAR 2021	ULTRASOUND	Diagnostic	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:28:58

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

US3732023

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:28:58

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 ☐

US3732023

Folder: SAE USA-US102-2021-MRNA-1273-P301000009

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 22:19:25

Generated On: 10 Jun 2021 09:28:58

SAEID	USA-US102-2021-MRNA-1273-P301000009
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)	1

US3732023

Folder: SAE USA-US102-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 22:19:25

Generated On: 10 Jun 2021 09:28:58

SAEID	USA-US102-2021-MRNA-1273-P301000009
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)	1
Date of submission (Pre-filled from custom function)	27/APR/2021 10:02
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

US3732023 (Prod: eStudySite - La Mesa - PPDS)

US3732023

Form: Participant Creation

Generated On: 10 Jun 2021 09:28:58

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'US3732023'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	07 Aug 2020 18:44:09

US3732023

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:28:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	07 Aug 2020 22:50:39

US3732023

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '07 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 18:44:11

US3732023

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'Clinic (Clinic)'	Lauren Arnett (b) (4)	07 Aug 2020 22:50:39

**US3732023**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:28:58**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered 'SCRN'	System	07 Aug 2020 22:50:39

US3732023

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:28:58

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered (b) (6) 1948'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 18:44:12

US3732023

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:28:58

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered '71'	Lauren Arnett (b) (4)	07 Aug 2020 22:50:57



**US3732023**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:28:58**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered 'YEARS'	System	07 Aug 2020 22:50:57

**US3732023**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:28:58**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered '71'	System	07 Aug 2020 19:08:30

US3732023

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:28:58

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'Female (F)'	Lauren Arnett (b) (4)	07 Aug 2020 22:50:57

US3732023

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:28:58

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Lauren Arnett (b) (4)	07 Aug 2020 22:50:57

US3732023

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:28:58

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'I'	Lauren Arnett (b) (4)	07 Aug 2020 22:50:57

US3732023

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:28:58

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered '0'	Lauren Arnett (b) (4)	07 Aug 2020 22:50:57

**US3732023**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:28:58**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered '0'	Lauren Arnett (b) (4)	07 Aug 2020 22:50:57

**US3732023**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:28:58**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered '0'	Lauren Arnett (b) (4)	07 Aug 2020 22:50:57



US3732023

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:28:58

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered '0'	Lauren Arnett (b) (4)	07 Aug 2020 22:50:57

**US3732023**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:28:58**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered '0'	Lauren Arnett (b) (4)	07 Aug 2020 22:50:57

US3732023

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:28:58

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered empty.	Lauren Arnett (b) (4)	07 Aug 2020 22:50:57

**US3732023**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:28:58**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered '0'	Lauren Arnett (b) (4)	07 Aug 2020 22:50:57

US3732023

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:28:58

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered '0'	Lauren Arnett (b) (4)	07 Aug 2020 22:50:57

US3732023

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:28:58

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered '07 Aug 2020'	Lauren Arnett (b) (4)	07 Aug 2020 19:08:30

**US3732023**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered 'Aug 2020'	System	07 Aug 2020 19:08:30

US3732023

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered '2020'	System	07 Aug 2020 19:08:30



**US3732023**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:28:58**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'Amendment 1 (1)'	Lauren Arnett (b) (4)	07 Aug 2020 19:08:30

US3732023

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	07 Aug 2020 19:08:30

US3732023

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:28:58

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered empty.	Lauren Arnett (b) (4)	07 Aug 2020 19:08:30

US3732023

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:28:58

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered empty.	Lauren Arnett (b) (4)	07 Aug 2020 19:08:30

**US3732023**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:28:58**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'No (N)'	Lauren Arnett (b) (4)	07 Aug 2020 19:08:30

**US3732023**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:28:58**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 18:44:11

US3732023

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:28:58

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered 'I'	System	07 Aug 2020 19:08:37

US3732023

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	07 Aug 2020 19:08:37



US3732023

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:28:58

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	07 Aug 2020 22:51:11

US3732023

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:28:58

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Rubber sensitivity, LLT: Latex allergy - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 22:54:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 22:54:20
Data point term sent to Coder	System	07 Aug 2020 22:52:46
User entered 'latex allergy'	Lauren Arnett (b) (4)	07 Aug 2020 22:51:49

US3732023

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'un UNK 1980'	Lauren Arnett (b) (4)	07 Aug 2020 22:51:49

US3732023

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:28:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '0'	Lauren Arnett (b) (4)	07 Aug 2020 22:51:49

**US3732023**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:28:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	07 Aug 2020 22:51:49

**US3732023**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:28:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered empty.	Lauren Arnett (b) (4)	07 Aug 2020 22:51:49

**US3732023**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:28:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '0'	Lauren Arnett (b) (4)	07 Aug 2020 22:51:49

US3732023

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:28:58

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered 'Jan 1980'	System	07 Aug 2020 22:51:49



**US3732023**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered '1980'	System	07 Aug 2020 22:51:49

**US3732023**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered empty.	System	07 Aug 2020 22:51:49

**US3732023**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered empty.	System	07 Aug 2020 22:51:49

US3732023

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:28:58

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Allergic reaction to excipient, LLT: Allergic reaction to excipient - version MedDRA\23.0.	Coder Import (b) (4)	14 Aug 2020 09:27:21
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	14 Aug 2020 09:27:21
Data point term sent to Coder	System	07 Aug 2020 22:52:46
User entered 'gel capsule allergy'	Lauren Arnett (b) (4)	07 Aug 2020 22:52:06

US3732023

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'un UNK 2005'	Lauren Arnett (b) (4)	07 Aug 2020 22:52:06

**US3732023**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:28:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '0'	Lauren Arnett (b) (4)	07 Aug 2020 22:52:06

US3732023

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:28:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	07 Aug 2020 22:52:06

**US3732023**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:28:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered empty.	Lauren Arnett (b) (4)	07 Aug 2020 22:52:06



**US3732023**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:28:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '0'	Lauren Arnett (b) (4)	07 Aug 2020 22:52:06

**US3732023**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered 'Jan 2005'	System	07 Aug 2020 22:52:06

**US3732023**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered '2005'	System	07 Aug 2020 22:52:06

US3732023

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered empty.	System	07 Aug 2020 22:52:06

**US3732023**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered empty.	System	07 Aug 2020 22:52:06

US3732023

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:28:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4)	25 Aug 2020 22:11:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	25 Aug 2020 22:11:41
Data point term sent to Coder	System	07 Aug 2020 22:52:46
User entered 'steroids allergy'	Lauren Arnett (b) (4)	07 Aug 2020 22:52:20

**US3732023**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'un UNK 2019'	Lauren Arnett (b) (4)	07 Aug 2020 22:52:20

US3732023

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:28:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '0'	Lauren Arnett (b) (4)	07 Aug 2020 22:52:20



**US3732023**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:28:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	07 Aug 2020 22:52:20

**US3732023**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:28:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered empty.	Lauren Arnett (b) (4)	07 Aug 2020 22:52:20

**US3732023**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:28:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '0'	Lauren Arnett (b) (4)	07 Aug 2020 22:52:20

**US3732023**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered 'Jan 2019'	System	07 Aug 2020 22:52:20

**US3732023**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered '2019'	System	07 Aug 2020 22:52:20

**US3732023**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered empty.	System	07 Aug 2020 22:52:20

**US3732023**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered empty.	System	07 Aug 2020 22:52:20

US3732023

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:28:58

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Food allergy, LLT: Fruit allergy - version MedDRA\\23.0.	Coder Import (b) (4)	10 Aug 2020 18:09:17
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	10 Aug 2020 18:09:17
Data point term sent to Coder	System	07 Aug 2020 22:52:46
User entered 'avocado allergy'	Lauren Arnett (b) (4)	07 Aug 2020 22:52:34



US3732023

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'un UNK 2020'	Lauren Arnett (b) (4)	07 Aug 2020 22:52:34

**US3732023**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:28:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '0'	Lauren Arnett (b) (4)	07 Aug 2020 22:52:34

**US3732023**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:28:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	07 Aug 2020 22:52:34

US3732023

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered empty.	Lauren Arnett (b) (4)	07 Aug 2020 22:52:34

US3732023

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:28:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '0'	Lauren Arnett (b) (4)	07 Aug 2020 22:52:34

**US3732023**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered 'Jan 2020'	System	07 Aug 2020 22:52:34

**US3732023**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered '2020'	System	07 Aug 2020 22:52:34

**US3732023**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered empty.	System	07 Aug 2020 22:52:34



**US3732023**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered empty.	System	07 Aug 2020 22:52:34

US3732023

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:28:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Food allergy, LLT: Fruit allergy - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 22:54:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 22:54:20
Data point term sent to Coder	System	07 Aug 2020 22:53:48
User entered 'pineapple allergy'	Lauren Arnett (b) (4)	07 Aug 2020 22:52:48

US3732023

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'un UNK 2020'	Lauren Arnett (b) (4)	07 Aug 2020 22:52:48

**US3732023**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:28:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '0'	Lauren Arnett (b) (4)	07 Aug 2020 22:52:48

**US3732023**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:28:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	07 Aug 2020 22:52:48

US3732023

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered empty.	Lauren Arnett (b) (4)	07 Aug 2020 22:52:48

**US3732023**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:28:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '0'	Lauren Arnett (b) (4)	07 Aug 2020 22:52:48

**US3732023**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered 'Jan 2020'	System	07 Aug 2020 22:52:48



**US3732023**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered '2020'	System	07 Aug 2020 22:52:48

**US3732023**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered empty.	System	07 Aug 2020 22:52:48

**US3732023**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered empty.	System	07 Aug 2020 22:52:48

US3732023

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:28:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Food allergy, LLT: Fruit allergy - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 00:11:19
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 00:11:19
Data point term sent to Coder	System	07 Aug 2020 22:53:47
User entered 'mango allergy'	Lauren Arnett (b) (4)	07 Aug 2020 22:53:01

**US3732023**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'un UNK 2020'	Lauren Arnett (b) (4)	07 Aug 2020 22:53:01

US3732023

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:28:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '0'	Lauren Arnett (b) (4)	07 Aug 2020 22:53:01

**US3732023**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:28:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	07 Aug 2020 22:53:01

**US3732023**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:28:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered empty.	Lauren Arnett (b) (4)	07 Aug 2020 22:53:01



**US3732023**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:28:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '0'	Lauren Arnett (b) (4)	07 Aug 2020 22:53:01

**US3732023**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered 'Jan 2020'	System	07 Aug 2020 22:53:01

**US3732023**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered '2020'	System	07 Aug 2020 22:53:01

**US3732023**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered empty.	System	07 Aug 2020 22:53:01

**US3732023**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered empty.	System	07 Aug 2020 22:53:01

US3732023

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:28:58

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Allergy to chemicals, LLT: Alcohol allergy - version MedDRA\\23.0.	Coder Import (b) (4)	21 Sep 2020 20:11:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	21 Sep 2020 20:11:51
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Food allergy, LLT: Food allergy - version MedDRA\\23.0.	Coder Import (b) (4)	10 Aug 2020 14:31:26
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	10 Aug 2020 14:31:26
Data point term sent to Coder	System	07 Aug 2020 22:53:46
User entered 'wine allergy'	Lauren Arnett (b) (4)	07 Aug 2020 22:53:15

US3732023

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'un UNK 1980'	Lauren Arnett (b) (4)	07 Aug 2020 22:53:15

**US3732023**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:28:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '0'	Lauren Arnett (b) (4)	07 Aug 2020 22:53:15



**US3732023**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:28:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	07 Aug 2020 22:53:15

US3732023

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered empty.	Lauren Arnett (b) (4)	07 Aug 2020 22:53:15

**US3732023**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:28:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '0'	Lauren Arnett (b) (4)	07 Aug 2020 22:53:15

**US3732023**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered 'Jan 1980'	System	07 Aug 2020 22:53:15

**US3732023**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered '1980'	System	07 Aug 2020 22:53:15

**US3732023**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered empty.	System	07 Aug 2020 22:53:15

**US3732023**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered empty.	System	07 Aug 2020 22:53:15

US3732023

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:28:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Food allergy, LLT: Food allergy - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 08:22:15
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 08:22:15
Data point term sent to Coder	System	07 Aug 2020 22:53:48
User entered 'swiss cheese allergy'	Lauren Arnett (b) (4)	07 Aug 2020 22:53:33



US3732023

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'un UNK 2020'	Lauren Arnett (b) (4)	07 Aug 2020 22:53:33

**US3732023**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:28:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '0'	Lauren Arnett (b) (4)	07 Aug 2020 22:53:33

**US3732023**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:28:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	07 Aug 2020 22:53:33

**US3732023**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:28:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered empty.	Lauren Arnett (b) (4)	07 Aug 2020 22:53:33

US3732023

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:28:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '0'	Lauren Arnett (b) (4)	07 Aug 2020 22:53:33

**US3732023**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered 'Jan 2020'	System	07 Aug 2020 22:53:33

**US3732023**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered '2020'	System	07 Aug 2020 22:53:33

**US3732023**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered empty.	System	07 Aug 2020 22:53:33



**US3732023**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered empty.	System	07 Aug 2020 22:53:33

US3732023

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:28:58

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User closed query 'Per DM CLR : Please review this MH and consider recording the underlying medical condition instead of test results. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Oct 2020 08:14:11
Query 'Per DM CLR : Please review this MH and consider recording the underlying medical condition instead of test results. Update eCRF as appropriate. ' answered with 'data entered is correct as is, chest x-ray confirmed negative' (Site from DM).	Lauren Arnett (b) (4) (b) (4)	02 Oct 2020 19:46:57
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 09:36:49
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'correct as is, no medication taken within protocol defined window' (Site from DM).	Lauren Arnett (b) (4) (b) (4)	28 Sep 2020 20:17:53
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 06:54:42
User opened query 'Per DM CLR : Please review this MH and consider recording the underlying medical condition instead of test results. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 06:54:31
User coded data point as SOC: Investigations, HLGT: Microbiology and serology investigations, HLT: Mycobacteria identification and serology, PT: Mycobacterium tuberculosis complex test positive, LLT: Tuberculosis test positive - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 17:33:18

US3732023

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:28:58

[Condition](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	17 Aug 2020 17:33:18
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	17 Aug 2020 17:32:11
Coding entries removed.	Lauren Arnett (b) (4)	17 Aug 2020 17:31:27
	(b) (4)	
User entered 'POSITIVE TUBERCULOSIS TEST'	Lauren Arnett (b) (4)	17 Aug 2020 17:31:27
reason for change: Data Entry Error	(b) (4)	
User coded data point as SOC: Investigations,	Coder Import (b) (4)	12 Aug 2020 12:56:26
HLGT: Microbiology and serology investigations,	(b) (4)	
HLT: Mycobacteria identification and serology, PT:		
Mycobacterium tuberculosis complex test positive,		
LLT: Tuberculosis test positive - version		
MedDRA\\23.0.		
User coded data point as Term Coded data point by	Coder Import (b) (4)	12 Aug 2020 12:56:26
User: (b) (6) - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	07 Aug 2020 22:54:48
User entered 'history of positive tuberculosis test'	Lauren Arnett (b) (4)	07 Aug 2020 22:54:07
	(b) (4)	

**US3732023**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'un UNK 1960'	Lauren Arnett (b) (4)	07 Aug 2020 22:54:07

**US3732023**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:28:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '0'	Lauren Arnett (b) (4)	07 Aug 2020 22:54:07

**US3732023**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:28:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	07 Aug 2020 22:54:07

US3732023

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered empty.	Lauren Arnett (b) (4)	07 Aug 2020 22:54:07

US3732023

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:28:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '0'	Lauren Arnett (b) (4)	07 Aug 2020 22:54:07



**US3732023**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered 'Jan 1960'	System	07 Aug 2020 22:54:07

**US3732023**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered '1960'	System	07 Aug 2020 22:54:07

US3732023

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered empty.	System	07 Aug 2020 22:54:07

**US3732023**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered empty.	System	07 Aug 2020 22:54:07

US3732023

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:28:58

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Hearing disorders, HLT: Hearing losses, PT: Deafness bilateral, LLT: Hearing loss bilateral - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 22:56:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 22:56:21
Data point term sent to Coder	System	07 Aug 2020 22:54:48
User entered 'bilateral hearing loss'	Lauren Arnett (b) (4)	07 Aug 2020 22:54:37

**US3732023**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'un UNK 2019'	Lauren Arnett (b) (4)	07 Aug 2020 22:54:37

US3732023

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:28:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '0'	Lauren Arnett (b) (4)	07 Aug 2020 22:54:37

**US3732023**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:28:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	07 Aug 2020 22:54:37



**US3732023**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:28:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered empty.	Lauren Arnett (b) (4)	07 Aug 2020 22:54:37

**US3732023**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:28:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '0'	Lauren Arnett (b) (4)	07 Aug 2020 22:54:37

US3732023

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:28:58

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered 'Jan 2019'	System	07 Aug 2020 22:54:37

**US3732023**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered '2019'	System	07 Aug 2020 22:54:37

**US3732023**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered empty.	System	07 Aug 2020 22:54:37

**US3732023**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered empty.	System	07 Aug 2020 22:54:37

US3732023

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:28:58

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User closed query 'Per DM CLR: Please specify the eye laterality with MYOPIA (Left, Right or Bilateral). Review and update Med History eCRF as appropriate.	(b) (4), (b) (6)	05 Nov 2020 16:43:42
' (Site from DM).		
User coded data point as SOC: Eye disorders, HLGT: Coder Import Vision disorders, HLT: Refractive and accommodative disorders, PT: Myopia, LLT: Myopia - version MedDRA\\23.0.	(b) (4)	03 Nov 2020 23:00:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Nov 2020 23:00:27
Data point term sent to Coder	System	03 Nov 2020 22:59:51
Query 'Per DM CLR: Please specify the eye laterality with MYOPIA (Left, Right or Bilateral). Review and update Med History eCRF as appropriate.	(b) (4), (b) (6)	03 Nov 2020 22:59:40
' answered with 'Updated.' (Site from DM).		
Coding entries removed.	(b) (4), (b) (6)	03 Nov 2020 22:59:32
User entered 'MYOPIA - bilateral' reason for change: New Information		03 Nov 2020 22:59:32
User opened query 'Per DM CLR: Please specify the eye laterality with MYOPIA (Left, Right or Bilateral). Review and update Med History eCRF as appropriate.		28 Sep 2020 06:54:07
' (Site from DM).		
User coded data point as SOC: Eye disorders, HLGT: Coder Import Vision disorders, HLT: Refractive and accommodative disorders, PT: Myopia, LLT: Myopia - version MedDRA\\23.0.	(b) (4)	07 Aug 2020 22:56:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 22:56:22
Data point term sent to Coder	System	07 Aug 2020 22:55:49
User entered 'myopia'	Lauren Arnett (b) (4)	07 Aug 2020 22:54:51

US3732023

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'un UNK 1960'	Lauren Arnett (b) (4)	07 Aug 2020 22:54:51



**US3732023**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:28:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '0'	Lauren Arnett (b) (4)	07 Aug 2020 22:54:51

**US3732023**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:28:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	07 Aug 2020 22:54:51

US3732023

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered empty.	Lauren Arnett (b) (4)	07 Aug 2020 22:54:51

US3732023

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:28:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '0'	Lauren Arnett (b) (4)	07 Aug 2020 22:54:51

**US3732023**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered 'Jan 1960'	System	07 Aug 2020 22:54:51

**US3732023**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered '1960'	System	07 Aug 2020 22:54:51

US3732023

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered empty.	System	07 Aug 2020 22:54:51

**US3732023**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered empty.	System	07 Aug 2020 22:54:51



US3732023

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:28:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis knees - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 07:05:26
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 07:05:26
Data point term sent to Coder	System	07 Aug 2020 22:55:49
User entered 'bilateral osteoarthritis in knees'	Lauren Arnett (b) (4)	07 Aug 2020 22:55:28

US3732023

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'un UNK 1990'	Lauren Arnett (b) (4)	07 Aug 2020 22:55:28

**US3732023**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:28:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '0'	Lauren Arnett (b) (4)	07 Aug 2020 22:55:28

**US3732023**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:28:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'No (N)'	Lauren Arnett (b) (4)	07 Aug 2020 22:55:28

**US3732023**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:28:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'un UNK 2019'	Lauren Arnett (b) (4)	07 Aug 2020 22:55:28

**US3732023**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:28:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '0'	Lauren Arnett (b) (4)	07 Aug 2020 22:55:28

**US3732023**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered 'Jan 1990'	System	07 Aug 2020 22:55:28

**US3732023**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered '1990'	System	07 Aug 2020 22:55:28



**US3732023**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered 'Jan 2019'	System	07 Aug 2020 22:55:28

**US3732023**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered '2019'	System	07 Aug 2020 22:55:28

US3732023

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:28:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User coded data point as SOC: Psychiatric disorders, HLTGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 22:57:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 22:57:23
Data point term sent to Coder	System	07 Aug 2020 22:56:52
User entered 'insomnia'	Lauren Arnett (b) (4)	07 Aug 2020 22:55:54

**US3732023**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'un UNK 2019'	Lauren Arnett (b) (4)	07 Aug 2020 22:55:54

**US3732023**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:28:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '0'	Lauren Arnett (b) (4)	07 Aug 2020 22:55:54

**US3732023**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:28:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	07 Aug 2020 22:55:54

**US3732023**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:28:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered empty.	Lauren Arnett (b) (4)	07 Aug 2020 22:55:54

**US3732023**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:28:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '0'	Lauren Arnett (b) (4)	07 Aug 2020 22:55:54



**US3732023**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered 'Jan 2019'	System	07 Aug 2020 22:55:54

**US3732023**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered '2019'	System	07 Aug 2020 22:55:54

**US3732023**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered empty.	System	07 Aug 2020 22:55:54

**US3732023**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered empty.	System	07 Aug 2020 22:55:54

US3732023

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:28:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Borrelial infections, PT: Lyme disease, LLT: Lyme disease - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 22:57:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 22:57:22
Data point term sent to Coder	System	07 Aug 2020 22:56:52
User entered 'lyme disease'	Lauren Arnett (b) (4)	07 Aug 2020 22:56:40

US3732023

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'un UNK 2015'	Lauren Arnett (b) (4)	07 Aug 2020 22:56:40

**US3732023**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:28:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '0'	Lauren Arnett (b) (4)	07 Aug 2020 22:56:40

US3732023

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:28:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'No (N)' reason for change: Data Entry Error	Lauren Arnett (b) (4)	07 Aug 2020 22:59:23
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	07 Aug 2020 22:56:40



US3732023

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'un UNK 2015' reason for change:	(b) (4)	
Data Entry Error	Lauren Arnett (b) (4)	07 Aug 2020 22:59:23
User entered empty.	(b) (4)	
	Lauren Arnett (b) (4)	07 Aug 2020 22:56:40
	(b) (4)	

US3732023

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:28:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '0'	Lauren Arnett (b) (4)	07 Aug 2020 22:56:40

**US3732023**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered 'Jan 2015'	System	07 Aug 2020 22:56:40

US3732023

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:28:58

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered '2015'	System	07 Aug 2020 22:56:40

**US3732023**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered 'Jan 2015'	System	07 Aug 2020 22:59:23
User entered empty.	System	07 Aug 2020 22:56:40

**US3732023**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered '2015'	System	07 Aug 2020 22:59:23
User entered empty.	System	07 Aug 2020 22:56:40

US3732023

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:28:58

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 08:15:31
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'data entered is correct as is, no associated medical history ' (Site from DM).	Lauren Arnett (b) (4)	02 Oct 2020 19:49:07
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 06:53:48
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 22:59:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 22:59:25
Data point term sent to Coder	System	07 Aug 2020 22:57:52
User entered 'hysterectomy'	Lauren Arnett (b) (4)	07 Aug 2020 22:56:58

US3732023

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'un UNK 1990'	Lauren Arnett (b) (4)	07 Aug 2020 22:56:58



US3732023

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:28:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '0'	Lauren Arnett (b) (4)	07 Aug 2020 22:56:58

**US3732023**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:28:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'No (N)' reason for change: New Information	(b) (4) Lauren Arnett (b) (4)	10 Aug 2020 19:18:48
User entered 'Yes (Y)'	(b) (4) Lauren Arnett (b) (4)	07 Aug 2020 22:56:58

US3732023

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'un UNK 1990' reason for change: New Information	(b) (4) Lauren Arnett (b) (4)	10 Aug 2020 19:18:48
User entered empty.	(b) (4) Lauren Arnett (b) (4)	07 Aug 2020 22:56:58

**US3732023**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:28:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '0'	Lauren Arnett (b) (4)	07 Aug 2020 22:56:58

**US3732023**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered 'Jan 1990'	System	07 Aug 2020 22:56:58

**US3732023**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered '1990'	System	07 Aug 2020 22:56:58

US3732023

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered 'Jan 1990'	System	10 Aug 2020 19:18:48
User entered empty.	System	07 Aug 2020 22:56:58

**US3732023**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered '1990'	System	10 Aug 2020 19:18:48
User entered empty.	System	07 Aug 2020 22:56:58



US3732023

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:28:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Menopause, LLT: Menopause - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 22:59:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 22:59:25
Data point term sent to Coder	System	07 Aug 2020 22:57:52
User entered 'menopause'	Lauren Arnett (b) (4)	07 Aug 2020 22:57:13

US3732023

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'un UNK 1990'	Lauren Arnett (b) (4)	07 Aug 2020 22:57:13

US3732023

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 09:28:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '0'	Lauren Arnett (b) (4)	07 Aug 2020 22:57:13

**US3732023**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:28:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'No (N)' reason for change: Data Entry Error	Lauren Arnett (b) (4)	07 Aug 2020 22:59:06
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	07 Aug 2020 22:57:13

**US3732023**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'un UNK 1990' reason for change:	(b) (4)	
Data Entry Error	Lauren Arnett (b) (4)	07 Aug 2020 22:59:06
User entered empty.	(b) (4)	
	Lauren Arnett (b) (4)	07 Aug 2020 22:57:13
	(b) (4)	

**US3732023**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:28:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '0'	Lauren Arnett (b) (4)	07 Aug 2020 22:57:13

**US3732023**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered 'Jan 1990'	System	07 Aug 2020 22:57:13

**US3732023**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered '1990'	System	07 Aug 2020 22:57:13



**US3732023**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered 'Jan 1990'	System	07 Aug 2020 22:59:06
User entered empty.	System	07 Aug 2020 22:57:13

**US3732023**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered '1990'	System	07 Aug 2020 22:59:06
User entered empty.	System	07 Aug 2020 22:57:13

US3732023

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:28:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User coded data point as SOC: Social circumstances, HLT: Lifestyle issues, HLT: Alcohol product use, PT: Alcohol use, LLT: Alcohol use - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 22:59:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 22:59:24
Data point term sent to Coder	System	07 Aug 2020 22:57:53
User entered 'alcohol use'	Lauren Arnett (b) (4)	07 Aug 2020 22:57:27

**US3732023**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'un UNK 1969'	Lauren Arnett (b) (4)	07 Aug 2020 22:57:27

**US3732023**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:28:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '0'	Lauren Arnett (b) (4)	07 Aug 2020 22:57:27

**US3732023**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:28:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	07 Aug 2020 22:57:27

**US3732023**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:28:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered empty.	Lauren Arnett (b) (4)	07 Aug 2020 22:57:27

**US3732023**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:28:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '0'	Lauren Arnett (b) (4)	07 Aug 2020 22:57:27



US3732023

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:28:58

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered 'Jan 1969'	System	07 Aug 2020 22:57:27

US3732023

Folder: Screening

Form: Medical History (17)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered '1969'	System	07 Aug 2020 22:57:27

**US3732023**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered empty.	System	07 Aug 2020 22:57:27

**US3732023**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered empty.	System	07 Aug 2020 22:57:27

US3732023

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:28:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 17:34:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 17:34:07
Data point term sent to Coder	System	17 Aug 2020 17:33:16
User entered 'seasonal allergies'	Lauren Arnett (b) (4)	17 Aug 2020 17:32:52

US3732023

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'un UNK 2000'	Lauren Arnett (b) (4)	17 Aug 2020 17:32:52

US3732023

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:28:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '0'	Lauren Arnett (b) (4)	17 Aug 2020 17:32:52

**US3732023**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 09:28:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	17 Aug 2020 17:32:52



US3732023

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered empty.	Lauren Arnett (b) (4)	17 Aug 2020 17:32:52

**US3732023**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 09:28:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '0'	Lauren Arnett (b) (4)	17 Aug 2020 17:32:52

**US3732023**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered 'Jan 2000'	System	17 Aug 2020 17:32:52

**US3732023**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered '2000'	System	17 Aug 2020 17:32:52

US3732023

Folder: Screening

Form: Medical History (18)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered empty.	System	17 Aug 2020 17:32:52

**US3732023**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered empty.	System	17 Aug 2020 17:32:52

US3732023

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:28:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 16:28:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 16:28:37
Data point term sent to Coder	System	24 Aug 2020 16:28:02
User entered 'non-migraine headaches'	Lauren Arnett (b) (4)	24 Aug 2020 16:27:18

**US3732023**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'un UNK 2020'	Lauren Arnett (b) (4)	24 Aug 2020 16:27:18



US3732023

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:28:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '0'	Lauren Arnett (b) (4)	24 Aug 2020 16:27:18

**US3732023**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:28:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	24 Aug 2020 16:27:18

US3732023

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered empty.	Lauren Arnett (b) (4)	24 Aug 2020 16:27:18

US3732023

Folder: Screening

Form: Medical History (19)

Generated On: 10 Jun 2021 09:28:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '0'	Lauren Arnett (b) (4)	24 Aug 2020 16:27:18

**US3732023**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered 'Jan 2020'	System	24 Aug 2020 16:27:18

**US3732023**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered '2020'	System	24 Aug 2020 16:27:18

**US3732023**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered empty.	System	24 Aug 2020 16:27:18

**US3732023**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered empty.	System	24 Aug 2020 16:27:18



US3732023

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:28:58

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
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: Back pain - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 16:28:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 16:28:37
Data point term sent to Coder	System	24 Aug 2020 16:28:02
User entered 'back pain'	Lauren Arnett (b) (4)	24 Aug 2020 16:27:31

US3732023

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'un UNK 2020'	Lauren Arnett (b) (4)	24 Aug 2020 16:27:31

US3732023

Folder: Screening

Form: Medical History (20)

Generated On: 10 Jun 2021 09:28:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '0'	Lauren Arnett (b) (4)	24 Aug 2020 16:27:31

**US3732023**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 09:28:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	24 Aug 2020 16:27:31

**US3732023**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 09:28:58**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered empty.	Lauren Arnett (b) (4)	24 Aug 2020 16:27:31

**US3732023**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 09:28:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '0'	Lauren Arnett (b) (4)	24 Aug 2020 16:27:31

**US3732023**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered 'Jan 2020'	System	24 Aug 2020 16:27:31

**US3732023**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered '2020'	System	24 Aug 2020 16:27:31



**US3732023**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered empty.	System	24 Aug 2020 16:27:31

**US3732023**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered empty.	System	24 Aug 2020 16:27:31

US3732023

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:28:58

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation - version MedDRA\\23.0.	Coder Import (b) (4)	01 Dec 2020 21:40:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Dec 2020 21:40:54
Data point term sent to Coder	System	01 Dec 2020 21:39:52
User entered 'constipation'	Amara Yilmaz (b) (4)	01 Dec 2020 21:39:38
	(b) (4)	

US3732023

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'un UNK 1970'	Amara Yilmaz (b) (4)	01 Dec 2020 21:39:38

**US3732023**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 09:28:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '0'	Amara Yilmaz (b) (4)	01 Dec 2020 21:39:38

**US3732023**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 09:28:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'Yes (Y)'	Amara Yilmaz (b) (4)	01 Dec 2020 21:39:38

US3732023

Folder: Screening

Form: Medical History (21)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered empty.	Amara Yilmaz (b) (4)	01 Dec 2020 21:39:38

**US3732023**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 09:28:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '0'	Amara Yilmaz (b) (4)	01 Dec 2020 21:39:38



**US3732023**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered 'Jan 1970'	System	01 Dec 2020 21:39:38

**US3732023**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered '1970'	System	01 Dec 2020 21:39:38

**US3732023**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered empty.	System	01 Dec 2020 21:39:38

**US3732023**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered empty.	System	01 Dec 2020 21:39:38

US3732023

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:28:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	15 Dec 2020 19:16:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Dec 2020 19:16:56
Data point term sent to Coder	System	15 Dec 2020 19:16:09
User entered 'post-menopausal'	Amara Yilmaz (b) (4)	15 Dec 2020 19:15:24

**US3732023**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'un UNK 1990'	Amara Yilmaz (b) (4)	15 Dec 2020 19:15:24

**US3732023**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 09:28:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '0'	Amara Yilmaz (b) (4)	15 Dec 2020 19:15:24

**US3732023**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 09:28:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'Yes (Y)'	Amara Yilmaz (b) (4)	15 Dec 2020 19:15:24



US3732023

Folder: Screening

Form: Medical History (22)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered empty.	Amara Yilmaz (b) (4)	15 Dec 2020 19:15:24

**US3732023**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 09:28:58**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '0'	Amara Yilmaz (b) (4)	15 Dec 2020 19:15:24

**US3732023**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered 'Jan 1990'	System	15 Dec 2020 19:15:24

**US3732023**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered '1990'	System	15 Dec 2020 19:15:24

**US3732023**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered empty.	System	15 Dec 2020 19:15:24

**US3732023**

**Folder: Screening**

**Form: Medical History (22)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered empty.	System	15 Dec 2020 19:15:24

US3732023

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:28:58

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 13:59:39
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'DM, see MedHx log #12. ' (Site from DM).	He (Helen) Pu (b) (4) (b) (4)	07 Apr 2021 18:31:20
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Apr 2021 11:33:43
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	31 Mar 2021 22:55:22
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee arthroplasty, LLT: Total knee replacement - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Mar 2021 22:57:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Mar 2021 22:57:14
Data point term sent to Coder	System	29 Mar 2021 22:56:23
User entered 'Bilateral Knee Replacement'	Sylvia Lindholm (b) (4) (b) (4)	29 Mar 2021 22:55:58

US3732023

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
User entered 'un Aug 2019'	(b) (4) Sylvia Lindholm (b) (4)	29 Mar 2021 22:55:58



US3732023

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:28:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
User entered '0'	(b) (4) Sylvia Lindholm (b) (4)	29 Mar 2021 22:55:58

**US3732023**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 10 Jun 2021 09:28:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
User entered 'No (N)'	(b) (4) Sylvia Lindholm (b) (4)	29 Mar 2021 22:55:58

US3732023

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
User entered 'un Aug 2019'	(b) (4) Sylvia Lindholm (b) (4)	29 Mar 2021 22:55:58

US3732023

Folder: Screening

Form: Medical History (23)

Generated On: 10 Jun 2021 09:28:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
User entered '0'	(b) (4) Sylvia Lindholm (b) (4)	29 Mar 2021 22:55:58

**US3732023**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered 'Aug 2019'	System	29 Mar 2021 22:55:58

**US3732023**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered '2019'	System	29 Mar 2021 22:55:58

**US3732023**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered 'Aug 2019'	System	29 Mar 2021 22:55:58

**US3732023**

**Folder: Screening**

**Form: Medical History (23)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered '2019'	System	29 Mar 2021 22:55:58



US3732023

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:28:58

[Condition](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Polyarthritis, LLT: Generalized arthritis - version MedDRA\\23.0.	Coder Import (b) (4)	26 Apr 2021 23:32:48
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Apr 2021 23:32:48
	(b) (4)	
Data point term sent to Coder	System	26 Apr 2021 23:32:19
User entered 'general arthritis'	Linda Vega (b) (4)	26 Apr 2021 23:32:04
	(b) (4)	

US3732023

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered 'un UNK 1990'	Linda Vega (b) (4)	26 Apr 2021 23:32:04

US3732023

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:28:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered '0'	Linda Vega (b) (4)	26 Apr 2021 23:32:04

**US3732023**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 10 Jun 2021 09:28:58**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered 'Yes (Y)'	Linda Vega (b) (4)	26 Apr 2021 23:32:04

US3732023

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered empty.	Linda Vega (b) (4)	26 Apr 2021 23:32:04

US3732023

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:28:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered '0'	Linda Vega (b) (4)	26 Apr 2021 23:32:04
	(b) (4)	

US3732023

Folder: Screening

Form: Medical History (24)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered 'Jan 1990'	System	26 Apr 2021 23:32:04

**US3732023**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered '1990'	System	26 Apr 2021 23:32:04



**US3732023**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered empty.	System	26 Apr 2021 23:32:04

**US3732023**

**Folder: Screening**

**Form: Medical History (24)**

**Generated On: 10 Jun 2021 09:28:58**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered empty.	System	26 Apr 2021 23:32:04

US3732023

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	07 Aug 2020 23:03:45

US3732023

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '07 Aug 2020'	Lauren Arnett (b) (4)	07 Aug 2020 23:03:45

**US3732023**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:58**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '11:25'	Lauren Arnett (b) (4)	07 Aug 2020 23:03:45

**US3732023**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:58**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered '07 Aug 2020 11:25'	System	07 Aug 2020 23:03:45

US3732023

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:58

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '158.3' cm	(b) (4) Lauren Arnett (b) (4)	07 Aug 2020 23:03:45
DataPoint set to visible.	(b) (4) System	07 Aug 2020 19:08:37

US3732023

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:58

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '69.8' kg	(b) (4) Lauren Arnett (b) (4)	07 Aug 2020 23:03:45
DataPoint set to visible.	(b) (4) System	07 Aug 2020 19:08:37



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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:58

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
Amendment Manager: User entered '27.85439'	System	16 Sep 2020 23:47:54
User entered '27.9'	System	07 Aug 2020 23:03:45
DataPoint set to visible.	System	07 Aug 2020 19:08:37

**US3732023**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:58**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered 'kg/m2'	System	07 Aug 2020 23:03:45
DataPoint set to visible.	System	07 Aug 2020 19:08:37

US3732023

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	28 Aug 2020 23:52:07
User entered '98.5' F	Lauren Arnett (b) (4)	07 Aug 2020 23:03:45
	(b) (4)	

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered empty; reason for change Data Entry Error	(b) (4)	
	Lauren Arnett (b) (4)	28 Aug 2020 23:52:07
User entered 'Oral (Oral)'	(b) (4)	
	Lauren Arnett (b) (4)	07 Aug 2020 23:03:45
	(b) (4)	

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered empty.	Lauren Arnett (b) (4)	07 Aug 2020 23:03:45

US3732023

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	28 Aug 2020 23:52:07
User entered '56'	Lauren Arnett (b) (4)	07 Aug 2020 23:03:45
	(b) (4)	

**US3732023**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:58**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered 'bpm'	System	07 Aug 2020 23:03:45

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	28 Aug 2020 23:52:07
User entered '16'	Lauren Arnett (b) (4)	07 Aug 2020 23:03:45
	(b) (4)	



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Folder: Screening

Form: Vital Signs

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[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered 'breaths/min'	System	07 Aug 2020 23:03:45

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:58

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	28 Aug 2020 23:52:07
User entered '107'	Lauren Arnett (b) (4)	07 Aug 2020 23:03:45
	(b) (4)	

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered 'mmHg'	System	07 Aug 2020 23:03:45

US3732023

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:58

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	28 Aug 2020 23:52:07
User entered '67'	Lauren Arnett (b) (4)	07 Aug 2020 23:03:45
	(b) (4)	

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:58

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered 'mmHg'	System	07 Aug 2020 23:03:45

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Folder: Screening

Form: Vital Signs

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[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:58

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38

US3732023

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:28:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	07 Aug 2020 23:04:13



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Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:28:58

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	11 Sep 2020 02:50:05
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	08 Sep 2020 16:24:58
User entered '07 Aug 2020'	Lauren Arnett (b) (4)	07 Aug 2020 23:04:13
	(b) (4)	

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:28:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered '07 Aug 2020'	Lauren Arnett (b) (4)	07 Aug 2020 23:05:08

US3732023

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:28:58

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'No (N)'	Lauren Arnett (b) (4)	07 Aug 2020 23:05:08

US3732023

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:28:58

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User closed query 'Per CDM: Per Sponsor request, supporting documentation for Post-Menopausal should be entered in MH. Thank you.' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 20:23:43
Query 'Per CDM: Per Sponsor request, supporting documentation for Post-Menopausal should be entered in MH. Thank you.' answered with 'post-menopausal has been recorded' (Site from DM).	Amara Yilmaz (b) (4)	15 Dec 2020 19:15:54
User opened query 'Per CDM: Per Sponsor request, supporting documentation for Post-Menopausal should be entered in MH. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 21:29:01
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Lauren Arnett (b) (4)	07 Aug 2020 23:05:08

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:28:58

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered empty.	Lauren Arnett (b) (4)	07 Aug 2020 23:05:08

US3732023

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered empty.	Lauren Arnett (b) (4)	07 Aug 2020 23:05:08

**US3732023**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:28:58**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered '0'	Lauren Arnett (b) (4)	07 Aug 2020 23:05:08

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'un UNK 1990'	Lauren Arnett (b) (4)	07 Aug 2020 23:05:08



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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:28:58

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered '0'	Lauren Arnett (b) (4)	07 Aug 2020 23:05:08

US3732023

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:58

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'No (N)'	Lauren Arnett (b) (4)	07 Aug 2020 23:05:59

US3732023

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:58

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'No (N)'	Lauren Arnett (b) (4)	07 Aug 2020 23:05:59

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:58

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'No (N)'	Lauren Arnett (b) (4)	07 Aug 2020 23:05:59

US3732023

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:58

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'No (N)'	Lauren Arnett (b) (4)	07 Aug 2020 23:05:59

US3732023

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:58

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'No (N)'	Lauren Arnett (b) (4)	07 Aug 2020 23:05:59

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:58

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'No (N)'	Lauren Arnett (b) (4)	07 Aug 2020 23:05:59

US3732023

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:58

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'No (N)'	Lauren Arnett (b) (4)	07 Aug 2020 23:05:59



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Folder: Screening

Form: Risk of Exposure

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**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'No (N)'	Lauren Arnett (b) (4)	07 Aug 2020 23:05:59

US3732023

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:58

**Hospitality and Tourism Workers** (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'No (N)'	Lauren Arnett (b) (4)	07 Aug 2020 23:05:59

US3732023

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:58

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'No (N)'	Lauren Arnett (b) (4)	07 Aug 2020 23:05:59

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Folder: Screening

Form: Risk of Exposure

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**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	07 Aug 2020 23:05:59

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Folder: Screening

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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'No (N)'	Lauren Arnett (b) (4)	07 Aug 2020 23:05:59

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered empty.	Lauren Arnett (b) (4)	07 Aug 2020 23:05:59

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Folder: Screening

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '0'	Lauren Arnett (b) (4)	07 Aug 2020 23:05:59

US3732023

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:58

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '0'	Lauren Arnett (b) (4)	07 Aug 2020 23:05:59



US3732023

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:58

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '0'	Lauren Arnett (b) (4)	07 Aug 2020 23:05:59

US3732023

Folder: Screening

Form: Risk of Exposure

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[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '0'	Lauren Arnett (b) (4)	07 Aug 2020 23:05:59

US3732023

Folder: Screening

Form: Risk of Exposure

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Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '0'	Lauren Arnett (b) (4)	07 Aug 2020 23:05:59

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:28:58

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'I'	Lauren Arnett (b) (4)	07 Aug 2020 23:05:59

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Folder: Screening

Form: Risk of Exposure

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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '0'	Lauren Arnett (b) (4)	07 Aug 2020 23:05:59

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered empty.	Lauren Arnett (b) (4)	07 Aug 2020 23:05:59

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Folder: Visit 1 Day 1

Form: Visit Date

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[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	07 Aug 2020 23:06:46

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:28:58

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '07 Aug 2020'	Lauren Arnett (b) (4)	07 Aug 2020 23:06:46



US3732023

Folder: Visit 1 Day 1

Form: Visit Date

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'Clinic (Clinic)'	Lauren Arnett (b) (4)	07 Aug 2020 23:06:46

**US3732023**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:28:58**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User entered 'VISIT1'	System	07 Aug 2020 23:06:46

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '07 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 18:44:16

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:28:58

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 02:57:14
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:57:13
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	07 Aug 2020 18:44:16
User entered '185237' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 18:44:16

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Folder: Visit 1 Day 1

Form: Randomization

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[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 18:44:16

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Folder: Visit 1 Day 1

Form: Randomization

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Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User closed query 'PER CDM: Please complete this section of the form.' (Site from DM).	(b) (4)	
Query 'PER CDM: Please complete this section of the form.' answered with 'complete ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 20:42:58
User entered 'No (N)'	Lauren Arnett (b) (4)	08 Sep 2020 16:24:10
	(b) (4)	
	Lauren Arnett (b) (4)	08 Sep 2020 16:24:02
	(b) (4)	
User opened query 'PER CDM: Please complete this section of the form.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 10:48:40

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Folder: Visit 1 Day 1

Form: Randomization

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Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'No (N)'	Lauren Arnett (b) (4)	08 Sep 2020 16:24:02

US3732023

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:28:58

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'No (N)'	Lauren Arnett (b) (4)	08 Sep 2020 16:24:02



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Folder: Visit 1 Day 1

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Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'No (N)'	Lauren Arnett (b) (4)	08 Sep 2020 16:24:02

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:28:58

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'No (N)'	Lauren Arnett (b) (4)	08 Sep 2020 16:24:02

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:28:58

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
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)	15 Sep 2020 17:52:41
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)	14 Sep 2020 22:53:06
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	14 Sep 2020 22:52:59
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)	11 Sep 2020 02:49:27
User entered empty; reason for change Data Entry Error	Lauren Arnett (b) (4)	28 Aug 2020 23:52:51
User entered '158.3' cm	Lauren Arnett (b) (4)	07 Aug 2020 23:08:02

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:28:58

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	14 Sep 2020 22:52:59
User entered empty; reason for change Data Entry Error	Lauren Arnett (b) (4)	28 Aug 2020 23:52:51
User entered '69.8' kg	Lauren Arnett (b) (4)	07 Aug 2020 23:08:02

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:28:58

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
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)	15 Sep 2020 17:52:41
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)	14 Sep 2020 22:53:06
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	14 Sep 2020 22:52:59
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)	11 Sep 2020 02:49:27
User entered empty; reason for change Data Entry Error	Lauren Arnett (b) (4)	28 Aug 2020 23:52:51
User entered '158.3' cm	Lauren Arnett (b) (4)	07 Aug 2020 23:08:02

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

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Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Lauren Arnett (b) (4)	14 Sep 2020 22:52:59
User entered empty; reason for change Data Entry Error	Lauren Arnett (b) (4)	28 Aug 2020 23:52:51
User entered '69.8' kg	(b) (4) Lauren Arnett (b) (4)	07 Aug 2020 23:08:02

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:58

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User accepted default value 'Pre-Dose (PREDOSE)'	Lauren Arnett (b) (4) (b) (4)	07 Aug 2020 23:08:02

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Lauren Arnett (b) (4)	28 Aug 2020 23:52:51
User entered 'No (N)'	(b) (4)	
	Lauren Arnett (b) (4)	07 Aug 2020 23:08:02
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '07 Aug 2020' reason for change: Data Entry Error	(b) (4)	
	Lauren Arnett (b) (4)	28 Aug 2020 23:52:51
User entered empty.	(b) (4)	
	Lauren Arnett (b) (4)	07 Aug 2020 23:08:02
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:58

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '11:25' reason for change: Data Entry Error	Lauren Arnett (b) (4)	28 Aug 2020 23:52:51
User entered empty.	Lauren Arnett (b) (4)	07 Aug 2020 23:08:02

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

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[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User entered '07 Aug 2020 11:25'	System	28 Aug 2020 23:52:51
User entered empty.	System	07 Aug 2020 23:08:02

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '98.5' F reason for change: Data Entry Error	(b) (4)	
	Lauren Arnett (b) (4)	28 Aug 2020 23:52:51
User entered empty.	(b) (4)	
	Lauren Arnett (b) (4)	07 Aug 2020 23:08:02
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	
	Lauren Arnett (b) (4)	28 Aug 2020 23:52:51
User entered empty.	(b) (4)	
	Lauren Arnett (b) (4)	07 Aug 2020 23:08:02
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered empty.	Lauren Arnett (b) (4)	07 Aug 2020 23:08:02

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '56' reason for change: Data Entry Error	(b) (4)	
	Lauren Arnett (b) (4)	28 Aug 2020 23:52:51
User entered empty.	(b) (4)	
	Lauren Arnett (b) (4)	07 Aug 2020 23:08:02
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User entered 'bpm'	System	28 Aug 2020 23:52:51
User entered empty.	System	07 Aug 2020 23:08:02



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '16' reason for change: Data Entry Error	Lauren Arnett (b) (4)	28 Aug 2020 23:52:51
User entered empty.	Lauren Arnett (b) (4)	07 Aug 2020 23:08:02

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User entered 'breaths/min'	System	28 Aug 2020 23:52:51
User entered empty.	System	07 Aug 2020 23:08:02

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '107' reason for change: Data Entry Error	Lauren Arnett (b) (4)	28 Aug 2020 23:52:51
User entered empty.	Lauren Arnett (b) (4)	07 Aug 2020 23:08:02

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User entered 'mmHg'	System	28 Aug 2020 23:52:51
User entered empty.	System	07 Aug 2020 23:08:02

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '67' reason for change: Data Entry Error	Lauren Arnett (b) (4)	28 Aug 2020 23:52:51
User entered empty.	Lauren Arnett (b) (4)	07 Aug 2020 23:08:02

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:58

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User entered 'mmHg'	System	28 Aug 2020 23:52:51
User entered empty.	System	07 Aug 2020 23:08:02

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:28:58

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
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)	15 Sep 2020 17:52:41
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)	14 Sep 2020 22:53:06
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	14 Sep 2020 22:52:59
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)	11 Sep 2020 02:49:27
User entered empty; reason for change Data Entry Error	Lauren Arnett (b) (4)	28 Aug 2020 23:52:51
User entered '158.3' cm	Lauren Arnett (b) (4)	07 Aug 2020 23:08:02

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Form: Vital Signs - Dosing

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Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Lauren Arnett (b) (4)	14 Sep 2020 22:52:59
User entered empty; reason for change Data Entry Error	Lauren Arnett (b) (4)	28 Aug 2020 23:52:51
User entered '69.8' kg	(b) (4) Lauren Arnett (b) (4)	07 Aug 2020 23:08:02



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:58

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User accepted default value 'Post-Dose (POSTDOSE)'	Lauren Arnett (b) (4) (b) (4)	07 Aug 2020 23:08:02

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	07 Aug 2020 23:08:02

US3732023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '07 Aug 2020'	Lauren Arnett (b) (4)	07 Aug 2020 23:08:02

US3732023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:58

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	10 Aug 2020 11:43:02
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'correctas is' (Site from System).	Lauren Arnett (b) (4)	07 Aug 2020 23:08:12
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4)	07 Aug 2020 23:08:02
User entered '12:36'	Lauren Arnett (b) (4)	07 Aug 2020 23:08:02

US3732023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:58

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User entered '07 Aug 2020 12:36'	System	07 Aug 2020 23:08:02

US3732023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '97.8' F	Lauren Arnett (b) (4)	07 Aug 2020 23:08:02

US3732023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'Oral (Oral)'	Lauren Arnett (b) (4)	07 Aug 2020 23:08:02

US3732023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered empty.	Lauren Arnett (b) (4)	07 Aug 2020 23:08:02



US3732023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '58'	Lauren Arnett (b) (4)	07 Aug 2020 23:08:02

US3732023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User entered 'bpm'	System	07 Aug 2020 23:08:02

US3732023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '14'	Lauren Arnett (b) (4)	07 Aug 2020 23:08:02

US3732023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User entered 'breaths/min'	System	07 Aug 2020 23:08:02

US3732023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '96'	Lauren Arnett (b) (4)	07 Aug 2020 23:08:02

US3732023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User entered 'mmHg'	System	07 Aug 2020 23:08:02

US3732023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '62'	Lauren Arnett (b) (4)	07 Aug 2020 23:08:02

US3732023

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:58

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User entered 'mmHg'	System	07 Aug 2020 23:08:02



US3732023

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:28:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'No (N)'	Lauren Arnett (b) (4)	07 Aug 2020 23:10:37

US3732023

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:28:58

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered empty.	Lauren Arnett (b) (4)	07 Aug 2020 23:10:37

US3732023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:28:58

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	07 Aug 2020 19:08:58

US3732023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:28:58

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered empty.	Lauren Arnett (b) (4)	07 Aug 2020 19:08:58

US3732023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered empty.	Lauren Arnett (b) (4)	07 Aug 2020 19:08:58

US3732023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:28:58

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User entered 'MRNA-1273 OR PLACEBO'	System	07 Aug 2020 19:08:58

US3732023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:28:58

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '07 Aug 2020'	Lauren Arnett (b) (4)	07 Aug 2020 19:08:58

US3732023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:28:58

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '12:06'	Lauren Arnett (b) (4)	07 Aug 2020 19:08:58



US3732023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:28:58

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User entered '07 Aug 2020 12:06'	System	07 Aug 2020 19:08:58

US3732023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:28:58

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'Left Arm (LEFT ARM)'	Lauren Arnett (b) (4)	07 Aug 2020 19:08:58

US3732023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:28:58

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User entered 'ONCE'	System	07 Aug 2020 19:08:58

US3732023

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:28:58

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User entered 'INTRAMUSCULAR'	System	07 Aug 2020 19:08:58

US3732023

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:28:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	07 Aug 2020 23:11:40

US3732023

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:28:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '07 Aug 2020'	Lauren Arnett (b) (4)	07 Aug 2020 23:11:40

US3732023

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:28:58

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '11:46'	Lauren Arnett (b) (4)	07 Aug 2020 23:11:40

US3732023

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:28:58

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User entered '07 Aug 2020 11:46'	System	07 Aug 2020 23:11:40



US3732023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:28:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '07 Aug 2020'	Lauren Arnett (b) (4)	07 Aug 2020 23:11:53

US3732023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:28:58

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Lauren Arnett (b) (4) (b) (4)	07 Aug 2020 23:11:53

US3732023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:28:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	07 Aug 2020 23:11:53

US3732023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:28:58

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '11:43'	Lauren Arnett (b) (4)	07 Aug 2020 23:11:53

**US3732023**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:28:58**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User entered '07 Aug 2020 11:43'	System	07 Aug 2020 23:11:53

US3732023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:28:58

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Lauren Arnett (b) (4) (b) (4)	07 Aug 2020 23:11:53

US3732023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:28:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'No (N)'	Lauren Arnett (b) (4)	07 Aug 2020 23:11:53

US3732023

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:28:58

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered empty.	Lauren Arnett (b) (4)	07 Aug 2020 23:11:53



**US3732023**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:28:58**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User entered empty.	System	07 Aug 2020 23:11:53

US3732023

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:28:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	07 Aug 2020 23:11:57

US3732023

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:28:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User entered 'I'	System	07 Aug 2020 23:11:57

US3732023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
Data entry locked.	System	07 Aug 2020 19:08:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 19:08:58

US3732023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:28:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-07T12:46:24', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'fad036a3-134c-4cf0-b1ff-b6cdf27c9daf'	System	07 Aug 2020 19:47:00
User entered 'Yes (Y)'	System	07 Aug 2020 19:47:00

US3732023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:28:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-07T12:46:36', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'fad036a3-134c-4cf0-b1ff-b6cdf27c9daf' User entered '97.8'	System	07 Aug 2020 19:47:00
	System	07 Aug 2020 19:47:00

US3732023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-07T12:46:44', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'fad036a3-134c-4cf0-b1ff-b6cdf27c9daf'	System	07 Aug 2020 19:47:00
User entered 'No (N)'	System	07 Aug 2020 19:47:00

US3732023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:28:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-07T12:46:57', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'fad036a3-134c-4cf0-b1ff-b6cdf27c9daf'	System	07 Aug 2020 19:47:00
User entered '07 Aug 2020 12:46'	System	07 Aug 2020 19:47:00



US3732023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:28:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '07 Aug 2020 12:26'	System	07 Aug 2020 19:08:58

US3732023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:28:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '07 Aug 2020 14:56'	System	07 Aug 2020 19:08:58

US3732023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
Data entry locked.	System	07 Aug 2020 19:08:58
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 19:08:58

US3732023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:28:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30

US3732023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:28:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30

US3732023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30

US3732023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30

US3732023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:28:58

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30



US3732023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:28:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30

US3732023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:28:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '07 Aug 2020 15:51'	System	07 Aug 2020 19:08:58

US3732023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:28:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 19:08:58

US3732023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
Data entry locked.	System	07 Aug 2020 19:08:58
User entered 'Day 2'	System	07 Aug 2020 19:08:58

US3732023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:28:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-08T19:46:04', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '10547e24-c437-491a-bb46-476839cb088d'	System	09 Aug 2020 02:46:48
User entered 'Yes (Y)'	System	09 Aug 2020 02:46:48

US3732023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:28:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-08T19:46:25', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '10547e24-c437-491a-bb46-476839cb088d' User entered '97.5'	System	09 Aug 2020 02:46:48
	System	09 Aug 2020 02:46:48

US3732023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-08T19:46:30', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '10547e24-c437-491a-bb46-476839cb088d'	System	09 Aug 2020 02:46:48
User entered 'No (N)'	System	09 Aug 2020 02:46:48

US3732023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:28:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-08T19:46:46', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '10547e24-c437-491a-bb46-476839cb088d'	System	09 Aug 2020 02:46:48
User entered '08 Aug 2020 19:46'	System	09 Aug 2020 02:46:48



US3732023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:28:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 19:08:58

US3732023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:28:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 19:08:58

US3732023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
Data entry locked.	System	07 Aug 2020 19:08:58
User entered 'Day 3'	System	07 Aug 2020 19:08:58

US3732023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:28:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-09T20:00:14', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'e9449f28-adb6-4a23-8ee5-6fec5c2809ed' User entered 'Yes (Y)'	System	10 Aug 2020 03:01:03
	System	10 Aug 2020 03:01:03

US3732023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:28:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-09T20:00:24', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'e9449f28-adb6-4a23-8ee5-6fec5c2809ed' User entered '98.4'	System	10 Aug 2020 03:01:03
	System	10 Aug 2020 03:01:03

US3732023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-09T20:00:40', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'e9449f28-adb6-4a23-8ee5-6fec5c2809ed' User entered 'No (N)'	System	10 Aug 2020 03:01:03
	System	10 Aug 2020 03:01:03

US3732023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:28:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-09T20:00:59', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'e9449f28-adb6-4a23-8ee5-6fec5c2809ed' User entered '09 Aug 2020 20:00'	System	10 Aug 2020 03:01:03
	System	10 Aug 2020 03:01:03

US3732023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:28:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 19:08:58



US3732023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:28:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 19:08:58

US3732023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
Data entry locked.	System	07 Aug 2020 19:08:58
User entered 'Day 4'	System	07 Aug 2020 19:08:58

US3732023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:28:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-10T23:50:11', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'f4fd6c06-667c-464b-9c84-6e05aebf18e7' User entered 'Yes (Y)'	System	11 Aug 2020 06:50:32
	System	11 Aug 2020 06:50:32

US3732023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:28:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-10T23:50:18', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'f4fd6c06-667c-464b-9c84-6e05aebf18e7' User entered '96.8'	System	11 Aug 2020 06:50:32
	System	11 Aug 2020 06:50:32

US3732023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-10T23:50:23', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'f4fd6c06-667c-464b-9c84-6e05aebf18e7'	System	11 Aug 2020 06:50:32
User entered 'No (N)'	System	11 Aug 2020 06:50:32

US3732023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:28:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-10T23:50:29', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'f4fd6c06-667c-464b-9c84-6e05aebf18e7' User entered '10 Aug 2020 23:50'	System	11 Aug 2020 06:50:32
	System	11 Aug 2020 06:50:32

US3732023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:28:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 19:08:58

US3732023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:28:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 19:08:58



US3732023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
Data entry locked.	System	07 Aug 2020 19:08:58
User entered 'Day 5'	System	07 Aug 2020 19:08:58

US3732023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:28:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-11T22:40:06', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '9aa1a79d-b5db-43b0-84bd-cdb8f7e54e72' User entered 'Yes (Y)'	System	12 Aug 2020 05:41:06
	System	12 Aug 2020 05:41:06

US3732023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:28:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-11T22:40:18', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '9aa1a79d-b5db-43b0-84bd-cdb8f7e54e72' User entered '97.4'	System	12 Aug 2020 05:41:06
	System	12 Aug 2020 05:41:06

US3732023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-11T22:40:23', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '9aa1a79d-b5db-43b0-84bd-cdb8f7e54e72'	System	12 Aug 2020 05:41:06
User entered 'No (N)'	System	12 Aug 2020 05:41:06

US3732023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:28:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-11T22:41:02', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '9aa1a79d-b5db-43b0-84bd-cdb8f7e54e72' User entered '11 Aug 2020 22:41'	System	12 Aug 2020 05:41:06
	System	12 Aug 2020 05:41:06

US3732023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:28:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 19:08:58

US3732023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:28:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 19:08:58

US3732023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
Data entry locked.	System	07 Aug 2020 19:08:58
User entered 'Day 6'	System	07 Aug 2020 19:08:58



US3732023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:28:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-12T22:52:44', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '2bbc1f24-f92a-410f-b08f-bc2f0275fb3a' User entered 'Yes (Y)'	System	13 Aug 2020 05:53:05
	System	13 Aug 2020 05:53:05

US3732023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:28:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-12T22:52:52', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '2bbc1f24-f92a-410f-b08f-bc2f0275fb3a' User entered '97.6'	System	13 Aug 2020 05:53:05
	System	13 Aug 2020 05:53:05

US3732023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-12T22:52:57', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '2bbc1f24-f92a-410f-b08f-bc2f0275fb3a'	System	13 Aug 2020 05:53:05
User entered 'No (N)'	System	13 Aug 2020 05:53:05

US3732023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:28:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-12T22:53:02', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '2bbc1f24-f92a-410f-b08f-bc2f0275fb3a'	System	13 Aug 2020 05:53:05
User entered '12 Aug 2020 22:53'	System	13 Aug 2020 05:53:05

US3732023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:28:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 19:08:58

US3732023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:28:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 19:08:58

US3732023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
Data entry locked.	System	07 Aug 2020 19:08:58
User entered 'Day 7'	System	07 Aug 2020 19:08:58

US3732023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:28:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-13T22:15:05', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'db703706-8810-4564-b9e0-16d12aa76405'	System	14 Aug 2020 05:15:48
User entered 'Yes (Y)'	System	14 Aug 2020 05:15:48



US3732023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:28:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-13T22:15:29', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'db703706-8810-4564-b9e0-16d12aa76405'	System	14 Aug 2020 05:15:48
User entered '97.9'	System	14 Aug 2020 05:15:48

US3732023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-13T22:15:37', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'db703706-8810-4564-b9e0-16d12aa76405'	System	14 Aug 2020 05:15:48
User entered 'No (N)'	System	14 Aug 2020 05:15:48

US3732023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:28:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-13T22:15:44', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'db703706-8810-4564-b9e0-16d12aa76405'	System	14 Aug 2020 05:15:48
User entered '13 Aug 2020 22:15'	System	14 Aug 2020 05:15:48

US3732023

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:28:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 19:08:58

**US3732023**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:28:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 19:08:58

US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
Data entry locked.	System	07 Aug 2020 19:08:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 19:08:58

US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:28:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-07T12:47:11', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '99ff56f7-47d0-4030-84b3-c3b4a6873f22'	System	07 Aug 2020 19:47:44
User entered 'None (1)'	System	07 Aug 2020 19:47:44

US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:28:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-07T12:47:15', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '99ff56f7-47d0-4030-84b3-c3b4a6873f22'	System	07 Aug 2020 19:47:44
User entered 'No (N)'	System	07 Aug 2020 19:47:44



US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-07T12:47:21', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '99ff56f7-47d0-4030-84b3-c3b4a6873f22'	System	07 Aug 2020 19:47:44
User entered 'No (N)'	System	07 Aug 2020 19:47:44

US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:28:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-07T12:47:34', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '99ff56f7-47d0-4030-84b3-c3b4a6873f22'	System	07 Aug 2020 19:47:44
User entered 'None (1)'	System	07 Aug 2020 19:47:44

**US3732023**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:28:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-07T12:47:42', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '99ff56f7-47d0-4030-84b3-c3b4a6873f22'	System	07 Aug 2020 19:47:44
User entered '07 Aug 2020 12:47'	System	07 Aug 2020 19:47:44

US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:28:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '07 Aug 2020 12:26'	System	07 Aug 2020 19:08:58

US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:28:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '07 Aug 2020 14:56'	System	07 Aug 2020 19:08:58

US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
Data entry locked.	System	07 Aug 2020 19:08:58
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 19:08:58

US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:28:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30

US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:28:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30



US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:28:58

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)	24 Feb 2021 19:58:30

US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30

US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:28:58

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)	24 Feb 2021 19:58:30

US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:28:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30

US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:28:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30

US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:28:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '07 Aug 2020 15:51'	System	07 Aug 2020 19:08:58

US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:28:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 19:08:58

US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
Data entry locked.	System	07 Aug 2020 19:08:58
User entered 'Day 2'	System	07 Aug 2020 19:08:58



US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:28:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-08T19:47:22', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'e163b2e3-7517-4546-8723-df4da73e17fb'	System	09 Aug 2020 02:47:54
User entered 'Does not interfere with activity (2)'	System	09 Aug 2020 02:47:54

US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:28:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-08T19:47:26', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'e163b2e3-7517-4546-8723-df4da73e17fb' User entered 'No (N)'	System	09 Aug 2020 02:47:54
	System	09 Aug 2020 02:47:54

US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-08T19:47:31', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'e163b2e3-7517-4546-8723-df4da73e17fb' User entered 'No (N)'	System	09 Aug 2020 02:47:54
	System	09 Aug 2020 02:47:54

US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:28:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-08T19:47:43', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'e163b2e3-7517-4546-8723-df4da73e17fb' User entered 'None (1)'	System	09 Aug 2020 02:47:54
	System	09 Aug 2020 02:47:54

US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:28:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-08T19:47:52', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'e163b2e3-7517-4546-8723-df4da73e17fb' User entered '08 Aug 2020 19:47'	System	09 Aug 2020 02:47:54
	System	09 Aug 2020 02:47:54

**US3732023**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:28:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 19:08:58

US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:28:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 19:08:58

US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
Data entry locked.	System	07 Aug 2020 19:08:58
User entered 'Day 3'	System	07 Aug 2020 19:08:58



US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:28:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-09T20:01:50', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'f2e729d8-228c-425e-867e-d3ff7c65a3db' User entered 'None (1)'	System	10 Aug 2020 03:02:40
	System	10 Aug 2020 03:02:40

US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:28:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-09T20:01:59', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'f2e729d8-228c-425e-867e-d3ff7c65a3db' User entered 'No (N)'	System	10 Aug 2020 03:02:40
	System	10 Aug 2020 03:02:40

US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-09T20:01:56', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'f2e729d8-228c-425e-867e-d3ff7c65a3db' User entered 'No (N)'	System	10 Aug 2020 03:02:40
	System	10 Aug 2020 03:02:40

US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:28:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-09T20:02:14', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'f2e729d8-228c-425e-867e-d3ff7c65a3db' User entered 'None (1)'	System	10 Aug 2020 03:02:40
	System	10 Aug 2020 03:02:40

US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:28:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-09T20:02:38', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'f2e729d8-228c-425e-867e-d3ff7c65a3db' User entered '09 Aug 2020 20:02'	System	10 Aug 2020 03:02:40
	System	10 Aug 2020 03:02:40

US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:28:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 19:08:58

US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:28:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 19:08:58

US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
Data entry locked.	System	07 Aug 2020 19:08:58
User entered 'Day 4'	System	07 Aug 2020 19:08:58



US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:28:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-10T23:50:35', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '91d1f087-d1aa-4ed5-b4a6-e6065a6be24a' User entered 'None (1)'	System	11 Aug 2020 06:50:54
	System	11 Aug 2020 06:50:54

US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:28:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-10T23:50:39', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '91d1f087-d1aa-4ed5-b4a6-e6065a6be24a' User entered 'No (N)'	System	11 Aug 2020 06:50:54
	System	11 Aug 2020 06:50:54

US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-10T23:50:41', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '91d1f087-d1aa-4ed5-b4a6-e6065a6be24a' User entered 'No (N)'	System	11 Aug 2020 06:50:54
	System	11 Aug 2020 06:50:54

US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:28:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-10T23:50:47', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '91d1f087-d1aa-4ed5-b4a6-e6065a6be24a' User entered 'None (1)'	System	11 Aug 2020 06:50:54
	System	11 Aug 2020 06:50:54

US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:28:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-10T23:50:51', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '91d1f087-d1aa-4ed5-b4a6-e6065a6be24a'	System	11 Aug 2020 06:50:54
User entered '10 Aug 2020 23:50'	System	11 Aug 2020 06:50:54

US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:28:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 19:08:58

US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:28:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 19:08:58

US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
Data entry locked.	System	07 Aug 2020 19:08:58
User entered 'Day 5'	System	07 Aug 2020 19:08:58



US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:28:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-11T22:41:11', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'a16787b2-6cd9-415d-9197-4e1d8aebaaf6'	System	12 Aug 2020 05:41:57
User entered 'None (1)'	System	12 Aug 2020 05:41:57

US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:28:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-11T22:41:22', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'a16787b2-6cd9-415d-9197-4e1d8aebaaf6' User entered 'No (N)'	System	12 Aug 2020 05:41:57
	System	12 Aug 2020 05:41:57

US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-11T22:41:28', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'a16787b2-6cd9-415d-9197-4e1d8aebaaf6' User entered 'No (N)'	System	12 Aug 2020 05:41:57
	System	12 Aug 2020 05:41:57

US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:28:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-11T22:41:33', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'a16787b2-6cd9-415d-9197-4e1d8aebaaf6'	System	12 Aug 2020 05:41:57
User entered 'None (1)'	System	12 Aug 2020 05:41:57

US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:28:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-11T22:41:55', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'a16787b2-6cd9-415d-9197-4e1d8aebaaf6'	System	12 Aug 2020 05:41:57
User entered '11 Aug 2020 22:41'	System	12 Aug 2020 05:41:57

US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:28:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 19:08:58

US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:28:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 19:08:58

US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
Data entry locked.	System	07 Aug 2020 19:08:58
User entered 'Day 6'	System	07 Aug 2020 19:08:58



US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:28:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-12T22:53:06', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'eefda9e6-b146-4f44-85f9-4a3212809d87'	System	13 Aug 2020 05:53:20
User entered 'None (1)'	System	13 Aug 2020 05:53:20

US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:28:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-12T22:53:09', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'eefda9e6-b146-4f44-85f9-4a3212809d87'	System	13 Aug 2020 05:53:20
User entered 'No (N)'	System	13 Aug 2020 05:53:20

US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-12T22:53:11', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'eefda9e6-b146-4f44-85f9-4a3212809d87'	System	13 Aug 2020 05:53:20
User entered 'No (N)'	System	13 Aug 2020 05:53:20

US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:28:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-12T22:53:15', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'eefda9e6-b146-4f44-85f9-4a3212809d87'	System	13 Aug 2020 05:53:20
User entered 'None (1)'	System	13 Aug 2020 05:53:20

US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:28:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-12T22:53:18', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'eefda9e6-b146-4f44-85f9-4a3212809d87'	System	13 Aug 2020 05:53:20
User entered '12 Aug 2020 22:53'	System	13 Aug 2020 05:53:20

US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:28:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 19:08:58

US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:28:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 19:08:58

US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
Data entry locked.	System	07 Aug 2020 19:08:58
User entered 'Day 7'	System	07 Aug 2020 19:08:58



US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:28:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-13T22:15:51', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '628a4966-c496-4bbd-b074-078104b1aed9' User entered 'None (1)'	System	14 Aug 2020 05:16:18
	System	14 Aug 2020 05:16:18

US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:28:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-13T22:16:04', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '628a4966-c496-4bbd-b074-078104b1aed9' User entered 'No (N)'	System	14 Aug 2020 05:16:18
	System	14 Aug 2020 05:16:18

US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-13T22:16:08', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '628a4966-c496-4bbd-b074-078104b1aed9' User entered 'No (N)'	System	14 Aug 2020 05:16:18
	System	14 Aug 2020 05:16:18

US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:28:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-13T22:16:12', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '628a4966-c496-4bbd-b074-078104b1aed9'	System	14 Aug 2020 05:16:18
User entered 'None (1)'	System	14 Aug 2020 05:16:18

US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:28:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-13T22:16:16', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '628a4966-c496-4bbd-b074-078104b1aed9' User entered '13 Aug 2020 22:16'	System	14 Aug 2020 05:16:18
	System	14 Aug 2020 05:16:18

US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:28:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 19:08:58

US3732023

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:28:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 19:08:58

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
Data entry locked.	System	07 Aug 2020 19:08:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 19:08:58



US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:58

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-07T12:47:50', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '8162d077-4213-4b48-8f81-860484560bf9' User entered 'None (0)'	System	07 Aug 2020 19:48:36
	System	07 Aug 2020 19:48:36

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:58

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-07T12:47:55', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '8162d077-4213-4b48-8f81-860484560bf9' User entered 'None (0)'	System	07 Aug 2020 19:48:36
	System	07 Aug 2020 19:48:36

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-07T12:48:04', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '8162d077-4213-4b48-8f81-860484560bf9' User entered 'None (0)'	System	07 Aug 2020 19:48:36
	System	07 Aug 2020 19:48:36

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-07T12:48:10', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '8162d077-4213-4b48-8f81-860484560bf9' User entered 'None (0)'	System	07 Aug 2020 19:48:36
	System	07 Aug 2020 19:48:36

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:58

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-07T12:48:13', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '8162d077-4213-4b48-8f81-860484560bf9' User entered 'None (0)'	System	07 Aug 2020 19:48:36
	System	07 Aug 2020 19:48:36

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:58

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-07T12:48:17', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '8162d077-4213-4b48-8f81-860484560bf9' User entered 'None (0)'	System	07 Aug 2020 19:48:36
	System	07 Aug 2020 19:48:36

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:58

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)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-07T12:48:25', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '8162d077-4213-4b48-8f81-860484560bf9' User entered 'No (N)'	System	07 Aug 2020 19:48:36
	System	07 Aug 2020 19:48:36

**US3732023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:28:58**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-07T12:48:33', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '8162d077-4213-4b48-8f81-860484560bf9' User entered '07 Aug 2020 12:48'	System	07 Aug 2020 19:48:36
	System	07 Aug 2020 19:48:36



US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '07 Aug 2020 12:26'	System	07 Aug 2020 19:08:58

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '07 Aug 2020 14:56'	System	07 Aug 2020 19:08:58

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
Data entry locked.	System	07 Aug 2020 19:08:58
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 19:08:58

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:58

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:58

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:58

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30



US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:58

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:58

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)	24 Feb 2021 19:58:30

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '07 Aug 2020 15:51'	System	07 Aug 2020 19:08:58

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 19:08:58

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
Data entry locked.	System	07 Aug 2020 19:08:58
User entered 'Day 2'	System	07 Aug 2020 19:08:58

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:58

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-08T19:48:20', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'fbdf7b6d-5d2a-4241-8651-37cf9db1f60c' User entered 'None (0)'	System	09 Aug 2020 02:49:44
	System	09 Aug 2020 02:49:44

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:58

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-08T19:48:23', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'fbdf7b6d-5d2a-4241-8651-37cf9db1f60c' User entered 'None (0)'	System	09 Aug 2020 02:49:44
	System	09 Aug 2020 02:49:44



US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-08T19:48:42', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'fbdf7b6d-5d2a-4241-8651-37cf9db1f60c' User entered 'None (0)'	System	09 Aug 2020 02:49:44
	System	09 Aug 2020 02:49:44

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-08T19:48:45', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'fbdf7b6d-5d2a-4241-8651-37cf9db1f60c' User entered 'None (0)'	System	09 Aug 2020 02:49:44
	System	09 Aug 2020 02:49:44

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:58

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-08T19:48:51', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'fbdf7b6d-5d2a-4241-8651-37cf9db1f60c' User entered 'None (0)'	System	09 Aug 2020 02:49:44
	System	09 Aug 2020 02:49:44

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:58

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-08T19:48:54', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'fbdf7b6d-5d2a-4241-8651-37cf9db1f60c' User entered 'None (0)'	System	09 Aug 2020 02:49:44
	System	09 Aug 2020 02:49:44

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:58

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)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-08T19:49:05', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'fbdf7b6d-5d2a-4241-8651-37cf9db1f60c'	System	09 Aug 2020 02:49:44
User entered 'No (N)'	System	09 Aug 2020 02:49:44

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-08T19:49:40', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'fbdf7b6d-5d2a-4241-8651-37cf9db1f60c' User entered '08 Aug 2020 19:49'	System	09 Aug 2020 02:49:44
	System	09 Aug 2020 02:49:44

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 19:08:58

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 19:08:58



US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
Data entry locked.	System	07 Aug 2020 19:08:58
User entered 'Day 3'	System	07 Aug 2020 19:08:58

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:58

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-09T20:02:50', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '9d4d5997-5dbe-4ad5-a772-d44ad44795af' User entered 'None (0)'	System	10 Aug 2020 03:04:26
	System	10 Aug 2020 03:04:26

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:58

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-09T20:02:58', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '9d4d5997-5dbe-4ad5-a772-d44ad44795af' User entered 'None (0)'	System	10 Aug 2020 03:04:26
	System	10 Aug 2020 03:04:26

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-09T20:03:04', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '9d4d5997-5dbe-4ad5-a772-d44ad44795af' User entered 'None (0)'	System	10 Aug 2020 03:04:26
	System	10 Aug 2020 03:04:26

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-09T20:03:10', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '9d4d5997-5dbe-4ad5-a772-d44ad44795af' User entered 'None (0)'	System	10 Aug 2020 03:04:26
	System	10 Aug 2020 03:04:26

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:58

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-09T20:03:15', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '9d4d5997-5dbe-4ad5-a772-d44ad44795af' User entered 'None (0)'	System	10 Aug 2020 03:04:26
	System	10 Aug 2020 03:04:26

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:58

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-09T20:03:54', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '9d4d5997-5dbe-4ad5-a772-d44ad44795af' User entered 'None (0)'	System	10 Aug 2020 03:04:26
	System	10 Aug 2020 03:04:26

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:58

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)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-09T20:04:02', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '9d4d5997-5dbe-4ad5-a772-d44ad44795af'	System	10 Aug 2020 03:04:26
User entered 'No (N)'	System	10 Aug 2020 03:04:26



**US3732023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:28:58**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-09T20:04:23', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '9d4d5997-5dbe-4ad5-a772-d44ad44795af' User entered '09 Aug 2020 20:04'	System	10 Aug 2020 03:04:26
	System	10 Aug 2020 03:04:26

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 19:08:58

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 19:08:58

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
Data entry locked.	System	07 Aug 2020 19:08:58
User entered 'Day 4'	System	07 Aug 2020 19:08:58

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:58

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-10T23:50:56', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'e4155372-8cbd-4941-be01-972b5d141eca' User entered 'None (0)'	System	11 Aug 2020 06:51:22
	System	11 Aug 2020 06:51:22

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:58

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-10T23:50:58', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'e4155372-8cbd-4941-be01-972b5d141eca' User entered 'None (0)'	System	11 Aug 2020 06:51:22
	System	11 Aug 2020 06:51:22

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-10T23:51:01', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'e4155372-8cbd-4941-be01-972b5d141eca' User entered 'None (0)'	System	11 Aug 2020 06:51:22
	System	11 Aug 2020 06:51:22

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-10T23:51:03', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'e4155372-8cbd-4941-be01-972b5d141eca' User entered 'None (0)'	System	11 Aug 2020 06:51:22
	System	11 Aug 2020 06:51:22



US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:58

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-10T23:51:06', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'e4155372-8cbd-4941-be01-972b5d141eca' User entered 'None (0)'	System	11 Aug 2020 06:51:22
	System	11 Aug 2020 06:51:22

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:58

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-10T23:51:08', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'e4155372-8cbd-4941-be01-972b5d141eca' User entered 'None (0)'	System	11 Aug 2020 06:51:22
	System	11 Aug 2020 06:51:22

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:58

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)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-10T23:51:13', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'e4155372-8cbd-4941-be01-972b5d141eca' User entered 'No (N)'	System	11 Aug 2020 06:51:22
	System	11 Aug 2020 06:51:22

**US3732023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:28:58**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-10T23:51:20', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'e4155372-8cbd-4941-be01-972b5d141eca' User entered '10 Aug 2020 23:51'	System	11 Aug 2020 06:51:22
	System	11 Aug 2020 06:51:22

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 19:08:58

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 19:08:58

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
Data entry locked.	System	07 Aug 2020 19:08:58
User entered 'Day 5'	System	07 Aug 2020 19:08:58

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:58

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-11T22:42:11', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '364f2dd0-7e0d-4cc7-aec5-b2174b415fa3' User entered 'None (0)'	System	12 Aug 2020 05:42:50
	System	12 Aug 2020 05:42:50



US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:58

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-11T22:42:14', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '364f2dd0-7e0d-4cc7-aec5-b2174b415fa3' User entered 'None (0)'	System	12 Aug 2020 05:42:50
	System	12 Aug 2020 05:42:50

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-11T22:42:17', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '364f2dd0-7e0d-4cc7-aec5-b2174b415fa3' User entered 'None (0)'	System	12 Aug 2020 05:42:50
	System	12 Aug 2020 05:42:50

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-11T22:42:20', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '364f2dd0-7e0d-4cc7-aec5-b2174b415fa3' User entered 'None (0)'	System	12 Aug 2020 05:42:50
	System	12 Aug 2020 05:42:50

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:58

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-11T22:42:25', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '364f2dd0-7e0d-4cc7-aec5-b2174b415fa3' User entered 'None (0)'	System	12 Aug 2020 05:42:50
	System	12 Aug 2020 05:42:50

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:58

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-11T22:42:27', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '364f2dd0-7e0d-4cc7-aec5-b2174b415fa3' User entered 'None (0)'	System	12 Aug 2020 05:42:50
	System	12 Aug 2020 05:42:50

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:58

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)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-11T22:42:32', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '364f2dd0-7e0d-4cc7-aec5-b2174b415fa3' User entered 'No (N)'	System	12 Aug 2020 05:42:50
	System	12 Aug 2020 05:42:50

**US3732023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:28:58**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-11T22:42:46', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '364f2dd0-7e0d-4cc7-aec5-b2174b415fa3'	System	12 Aug 2020 05:42:50
User entered '11 Aug 2020 22:42'	System	12 Aug 2020 05:42:50

**US3732023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:28:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 19:08:58



**US3732023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:28:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 19:08:58

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
Data entry locked.	System	07 Aug 2020 19:08:58
User entered 'Day 6'	System	07 Aug 2020 19:08:58

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:58

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-12T22:53:23', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'e5e84859-0ad7-43f6-961c-3c65f6a87d2e' User entered 'None (0)'	System	13 Aug 2020 05:53:48
	System	13 Aug 2020 05:53:48

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:58

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-12T22:53:25', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'e5e84859-0ad7-43f6-961c-3c65f6a87d2e' User entered 'None (0)'	System	13 Aug 2020 05:53:48
	System	13 Aug 2020 05:53:48

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-12T22:53:27', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'e5e84859-0ad7-43f6-961c-3c65f6a87d2e' User entered 'None (0)'	System	13 Aug 2020 05:53:48
	System	13 Aug 2020 05:53:48

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-12T22:53:29', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'e5e84859-0ad7-43f6-961c-3c65f6a87d2e' User entered 'None (0)'	System	13 Aug 2020 05:53:48
	System	13 Aug 2020 05:53:48

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:58

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-12T22:53:31', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'e5e84859-0ad7-43f6-961c-3c65f6a87d2e' User entered 'None (0)'	System	13 Aug 2020 05:53:48
	System	13 Aug 2020 05:53:48

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:58

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-12T22:53:33', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'e5e84859-0ad7-43f6-961c-3c65f6a87d2e' User entered 'None (0)'	System	13 Aug 2020 05:53:48
	System	13 Aug 2020 05:53:48



US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:58

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)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-12T22:53:36', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'e5e84859-0ad7-43f6-961c-3c65f6a87d2e' User entered 'No (N)'	System	13 Aug 2020 05:53:48
	System	13 Aug 2020 05:53:48

**US3732023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:28:58**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-12T22:53:43', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'e5e84859-0ad7-43f6-961c-3c65f6a87d2e' User entered '12 Aug 2020 22:53'	System	13 Aug 2020 05:53:48
	System	13 Aug 2020 05:53:48

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 19:08:58

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 19:08:58

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
Data entry locked.	System	07 Aug 2020 19:08:58
User entered 'Day 7'	System	07 Aug 2020 19:08:58

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:58

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-13T22:16:20', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '26ab3fea-4d22-4297-8a99-2ec7a172d763' User entered 'None (0)'	System	14 Aug 2020 05:16:52
	System	14 Aug 2020 05:16:52

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:58

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-13T22:16:22', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '26ab3fea-4d22-4297-8a99-2ec7a172d763' User entered 'None (0)'	System	14 Aug 2020 05:16:52
	System	14 Aug 2020 05:16:52

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-13T22:16:30', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '26ab3fea-4d22-4297-8a99-2ec7a172d763' User entered 'None (0)'	System	14 Aug 2020 05:16:52
	System	14 Aug 2020 05:16:52



US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-13T22:16:33', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '26ab3fea-4d22-4297-8a99-2ec7a172d763' User entered 'None (0)'	System	14 Aug 2020 05:16:52
	System	14 Aug 2020 05:16:52

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:58

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-13T22:16:37', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '26ab3fea-4d22-4297-8a99-2ec7a172d763' User entered 'None (0)'	System	14 Aug 2020 05:16:52
	System	14 Aug 2020 05:16:52

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:58

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-13T22:16:39', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '26ab3fea-4d22-4297-8a99-2ec7a172d763' User entered 'None (0)'	System	14 Aug 2020 05:16:52
	System	14 Aug 2020 05:16:52

US3732023

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:58

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)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-13T22:16:45', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '26ab3fea-4d22-4297-8a99-2ec7a172d763' User entered 'No (N)'	System	14 Aug 2020 05:16:52
	System	14 Aug 2020 05:16:52

**US3732023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:28:58**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-08-13T22:16:50', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '26ab3fea-4d22-4297-8a99-2ec7a172d763'	System	14 Aug 2020 05:16:52
User entered '13 Aug 2020 22:16'	System	14 Aug 2020 05:16:52

**US3732023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:28:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 19:08:58

**US3732023**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:28:58**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 19:08:58

US3732023

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	17 Aug 2020 17:29:40



US3732023

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:58

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered '14 Aug 2020'	Lauren Arnett (b) (4)	17 Aug 2020 17:29:40

US3732023

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'Contact Made (CONTACT MADE)'	Lauren Arnett (b) (4)	17 Aug 2020 17:29:40

US3732023

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:58

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered empty.	Lauren Arnett (b) (4)	17 Aug 2020 17:29:40

US3732023

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:28:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	17 Aug 2020 17:29:59

**US3732023**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:28:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User entered 'I'	System	17 Aug 2020 17:29:59

**US3732023**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:28:58**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	24 Aug 2020 16:19:04

US3732023

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:58

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered '21 Aug 2020'	Lauren Arnett (b) (4)	24 Aug 2020 16:19:04

US3732023

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'Contact Made (CONTACT MADE)'	Lauren Arnett (b) (4)	24 Aug 2020 16:19:04



US3732023

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:58

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered empty.	Lauren Arnett (b) (4)	24 Aug 2020 16:19:04

US3732023

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:28:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	24 Aug 2020 16:19:12

**US3732023**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:28:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User entered 'I'	System	24 Aug 2020 16:19:12

US3732023

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	28 Aug 2020 23:51:10

US3732023

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:58

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered '28 Aug 2020'	Lauren Arnett (b) (4)	28 Aug 2020 23:51:10

US3732023

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'Contact Made (CONTACT MADE)'	Lauren Arnett (b) (4)	28 Aug 2020 23:51:10

US3732023

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:58

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered empty.	Lauren Arnett (b) (4)	28 Aug 2020 23:51:10

US3732023

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:28:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	28 Aug 2020 23:51:24



US3732023

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:28:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User entered 'I'	System	28 Aug 2020 23:51:24

US3732023

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:28:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:14
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	08 Sep 2020 16:24:58

US3732023

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:14
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '04 Sep 2020'	Lauren Arnett (b) (4)	08 Sep 2020 16:24:58

US3732023

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:14
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'Clinic (Clinic)'	Lauren Arnett (b) (4)	08 Sep 2020 16:24:58

US3732023

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:28:58

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:14
User entered 'VISIT2'	System	08 Sep 2020 16:24:58

US3732023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:58

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:14
User accepted default value 'Pre-Dose (PREDOSE)'	Lauren Arnett (b) (4) (b) (4)	08 Sep 2020 16:26:12

US3732023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:14
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	08 Sep 2020 16:26:12

US3732023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:14
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '04 Sep 2020'	Lauren Arnett (b) (4)	08 Sep 2020 16:26:12



US3732023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:58

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:14
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '10:40'	Lauren Arnett (b) (4)	08 Sep 2020 16:26:12

US3732023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:58

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:14
User entered '04 Sep 2020 10:40'	System	08 Sep 2020 16:26:12

US3732023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:14
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '98.7' F	Lauren Arnett (b) (4)	08 Sep 2020 16:26:12

US3732023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:14
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'Oral (Oral)'	Lauren Arnett (b) (4)	08 Sep 2020 16:26:12

US3732023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:14
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered empty.	Lauren Arnett (b) (4)	08 Sep 2020 16:26:12

US3732023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:14
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '66'	Lauren Arnett (b) (4)	08 Sep 2020 16:26:12

US3732023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:14
User entered 'bpm'	System	08 Sep 2020 16:26:12

US3732023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:14
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '16'	Lauren Arnett (b) (4)	08 Sep 2020 16:26:12



US3732023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:14
User entered 'breaths/min'	System	08 Sep 2020 16:26:12

US3732023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:14
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '91'	Lauren Arnett (b) (4)	08 Sep 2020 16:26:12

US3732023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:14
User entered 'mmHg'	System	08 Sep 2020 16:26:12

US3732023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:14
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	09 Nov 2020 11:59:59
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'ncs per investigator however not a grade 3 per protocol ' (Site from System).	Lauren Arnett (b) (4)	06 Nov 2020 19:40:18
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:47:54
User entered '59'	Lauren Arnett (b) (4)	08 Sep 2020 16:26:12

US3732023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:28:58

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:14
User entered 'mmHg'	System	08 Sep 2020 16:26:12

US3732023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:58

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:14
User accepted default value 'Post-Dose (POSTDOSE)'	Lauren Arnett (b) (4) (b) (4)	08 Sep 2020 16:26:12

US3732023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:14
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	08 Sep 2020 16:26:12

US3732023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:14
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '04 Sep 2020'	Lauren Arnett (b) (4)	08 Sep 2020 16:26:12



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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:58

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:14
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '11:55'	Lauren Arnett (b) (4)	08 Sep 2020 16:26:12

US3732023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:58

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:14
User entered '04 Sep 2020 11:55'	System	08 Sep 2020 16:26:12

US3732023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:14
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '97.7' F	Lauren Arnett (b) (4)	08 Sep 2020 16:26:12

US3732023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:14
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'Oral (Oral)'	Lauren Arnett (b) (4)	08 Sep 2020 16:26:12

US3732023

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:14
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered empty.	Lauren Arnett (b) (4)	08 Sep 2020 16:26:12

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:14
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '57'	Lauren Arnett (b) (4)	08 Sep 2020 16:26:12

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:14
User entered 'bpm'	System	08 Sep 2020 16:26:12

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:14
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '14'	Lauren Arnett (b) (4)	08 Sep 2020 16:26:12



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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:14
User entered 'breaths/min'	System	08 Sep 2020 16:26:12

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:14
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '101'	Lauren Arnett (b) (4)	08 Sep 2020 16:26:12

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:14
User entered 'mmHg'	System	08 Sep 2020 16:26:12

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:14
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '64'	Lauren Arnett (b) (4)	08 Sep 2020 16:26:12

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:28:58

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:14
User entered 'mmHg'	System	08 Sep 2020 16:26:12

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Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:28:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:14
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	08 Sep 2020 16:26:19

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Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:28:58

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:14
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '04 Sep 2020'	Lauren Arnett (b) (4)	08 Sep 2020 16:26:19

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:28:58

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	04 Sep 2020 18:28:43



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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:28:58

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered empty.	Lauren Arnett (b) (4)	04 Sep 2020 18:28:43

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered empty.	Lauren Arnett (b) (4)	04 Sep 2020 18:28:43

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:28:58

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User entered 'MRNA-1273 OR PLACEBO'	System	04 Sep 2020 18:28:43

US3732023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:28:58

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '04 Sep 2020'	Lauren Arnett (b) (4)	04 Sep 2020 18:28:43

US3732023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:28:58

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '11:25'	Lauren Arnett (b) (4)	04 Sep 2020 18:28:43

US3732023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:28:58

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User entered '04 Sep 2020 11:25'	System	04 Sep 2020 18:28:43

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:28:58

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'Left Arm (LEFT ARM)'	Lauren Arnett (b) (4)	04 Sep 2020 18:28:43

US3732023

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:28:58

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User entered 'ONCE'	System	04 Sep 2020 18:28:43



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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:28:58

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User entered 'INTRAMUSCULAR'	System	04 Sep 2020 18:28:43

US3732023

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:28:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	08 Sep 2020 16:26:43

US3732023

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:28:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '04 Sep 2020'	Lauren Arnett (b) (4)	08 Sep 2020 16:26:43

US3732023

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:28:58

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '11:03'	Lauren Arnett (b) (4)	08 Sep 2020 16:26:43

US3732023

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:28:58

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User entered '04 Sep 2020 11:03'	System	08 Sep 2020 16:26:43

US3732023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:28:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '04 Sep 2020'	Lauren Arnett (b) (4)	08 Sep 2020 16:26:55

US3732023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:28:58

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Lauren Arnett (b) (4) (b) (4)	08 Sep 2020 16:26:55

US3732023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:28:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	08 Sep 2020 16:26:55



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Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:28:58

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '10:43'	Lauren Arnett (b) (4)	08 Sep 2020 16:26:55

**US3732023**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:28:58**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User entered '04 Sep 2020 10:43'	System	08 Sep 2020 16:26:55

US3732023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:28:58

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Lauren Arnett (b) (4) (b) (4)	08 Sep 2020 16:26:55

US3732023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:28:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'No (N)'	Lauren Arnett (b) (4)	08 Sep 2020 16:26:55

US3732023

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:28:58

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered empty.	Lauren Arnett (b) (4)	08 Sep 2020 16:26:55

**US3732023**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:28:58**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User entered empty.	System	08 Sep 2020 16:26:55

US3732023

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:28:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	08 Sep 2020 16:26:59

US3732023

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:28:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User entered '1'	System	08 Sep 2020 16:26:59



US3732023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
Data entry locked.	System	04 Sep 2020 18:28:43
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 18:28:43

US3732023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:28:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-04T12:01:06', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '00813e75-619c-4176-a074-6df935c13b2a' User entered 'Yes (Y)'	System	04 Sep 2020 19:01:38
	System	04 Sep 2020 19:01:38

US3732023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:28:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-04T12:01:19', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '00813e75-619c-4176-a074-6df935c13b2a' User entered '97.7'	System	04 Sep 2020 19:01:38
	System	04 Sep 2020 19:01:38

US3732023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-04T12:01:26', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '00813e75-619c-4176-a074-6df935c13b2a' User entered 'No (N)'	System	04 Sep 2020 19:01:38
	System	04 Sep 2020 19:01:38

US3732023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:28:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-04T12:01:32', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '00813e75-619c-4176-a074-6df935c13b2a' User entered '04 Sep 2020 12:01'	System	04 Sep 2020 19:01:38
	System	04 Sep 2020 19:01:38

US3732023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:28:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '04 Sep 2020 11:45'	System	04 Sep 2020 18:28:43

US3732023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:28:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '04 Sep 2020 14:15'	System	04 Sep 2020 18:28:43

US3732023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
Data entry locked.	System	04 Sep 2020 18:28:43
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 18:28:43



US3732023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:28:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-04T21:19:59', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '8cf5651a-c604-4058-9875-7cfd596727f9' User entered 'Yes (Y)'	System	05 Sep 2020 04:20:20
	System	05 Sep 2020 04:20:20

US3732023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:28:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-04T21:20:06', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '8cf5651a-c604-4058-9875-7cfd596727f9' User entered '98.1'	System	05 Sep 2020 04:20:20
	System	05 Sep 2020 04:20:20

US3732023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-04T21:20:12', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '8cf5651a-c604-4058-9875-7cfd596727f9' User entered 'No (N)'	System	05 Sep 2020 04:20:20
	System	05 Sep 2020 04:20:20

US3732023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:28:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-04T21:20:17', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '8cf5651a-c604-4058-9875-7cfd596727f9' User entered '04 Sep 2020 21:20'	System	05 Sep 2020 04:20:20
	System	05 Sep 2020 04:20:20

US3732023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:28:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '04 Sep 2020 15:10'	System	04 Sep 2020 18:28:43

US3732023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:28:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 18:28:43

US3732023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
Data entry locked.	System	04 Sep 2020 18:28:43
User entered 'Day 2'	System	04 Sep 2020 18:28:43

US3732023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:28:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-05T21:41:22', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '53a525bb-c633-4646-83bb-f59d7c77aa08' User entered 'Yes (Y)'	System	06 Sep 2020 04:41:43
	System	06 Sep 2020 04:41:43



US3732023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:28:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-05T21:41:29', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '53a525bb-c633-4646-83bb-f59d7c77aa08' User entered '99.9'	System	06 Sep 2020 04:41:43
	System	06 Sep 2020 04:41:43

US3732023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-05T21:41:35', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '53a525bb-c633-4646-83bb-f59d7c77aa08' User entered 'No (N)'	System	06 Sep 2020 04:41:43
	System	06 Sep 2020 04:41:43

US3732023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:28:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-05T21:41:40', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '53a525bb-c633-4646-83bb-f59d7c77aa08' User entered '05 Sep 2020 21:41'	System	06 Sep 2020 04:41:43
	System	06 Sep 2020 04:41:43

US3732023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:28:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 18:28:43

US3732023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:28:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 18:28:43

US3732023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
Data entry locked.	System	04 Sep 2020 18:28:43
User entered 'Day 3'	System	04 Sep 2020 18:28:43

US3732023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:28:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-06T19:49:24', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'f478c1a3-b5cf-436a-8830-5878dd5f4054' User entered 'Yes (Y)'	System	07 Sep 2020 02:49:44
	System	07 Sep 2020 02:49:44

US3732023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:28:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-06T19:49:33', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'f478c1a3-b5cf-436a-8830-5878dd5f4054' User entered '98.6'	System	07 Sep 2020 02:49:44
	System	07 Sep 2020 02:49:44



US3732023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-06T19:49:36', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'f478c1a3-b5cf-436a-8830-5878dd5f4054'	System	07 Sep 2020 02:49:44
User entered 'No (N)'	System	07 Sep 2020 02:49:44

US3732023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:28:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-06T19:49:40', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'f478c1a3-b5cf-436a-8830-5878dd5f4054' User entered '06 Sep 2020 19:49'	System	07 Sep 2020 02:49:44
	System	07 Sep 2020 02:49:44

US3732023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:28:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 18:28:43

US3732023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:28:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 18:28:43

US3732023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
Data entry locked.	System	04 Sep 2020 18:28:43
User entered 'Day 4'	System	04 Sep 2020 18:28:43

US3732023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:28:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-07T21:55:59', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '4c66add1-022c-427c-aea3-58c9f72f9b63' User entered 'Yes (Y)'	System	08 Sep 2020 04:56:15
	System	08 Sep 2020 04:56:15

US3732023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:28:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-07T21:56:05', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '4c66add1-022c-427c-aea3-58c9f72f9b63' User entered '98.2'	System	08 Sep 2020 04:56:15
	System	08 Sep 2020 04:56:15

US3732023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-07T21:56:08', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '4c66add1-022c-427c-aea3-58c9f72f9b63'	System	08 Sep 2020 04:56:15
User entered 'No (N)'	System	08 Sep 2020 04:56:15



US3732023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:28:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-07T21:56:12', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '4c66add1-022c-427c-aea3-58c9f72f9b63'	System	08 Sep 2020 04:56:15
User entered '07 Sep 2020 21:56'	System	08 Sep 2020 04:56:15

US3732023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:28:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 18:28:43

US3732023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:28:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 18:28:43

US3732023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
Data entry locked.	System	04 Sep 2020 18:28:43
User entered 'Day 5'	System	04 Sep 2020 18:28:43

US3732023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:28:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-09T00:04:36', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '1f0b7f35-1eb8-424f-9b89-41ba1a2549d4' User entered 'Yes (Y)'	System	09 Sep 2020 07:04:52
	System	09 Sep 2020 07:04:52

US3732023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:28:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-09T00:04:43', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '1f0b7f35-1eb8-424f-9b89-41ba1a2549d4' User entered '97.5'	System	09 Sep 2020 07:04:52
	System	09 Sep 2020 07:04:52

US3732023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-09T00:04:46', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '1f0b7f35-1eb8-424f-9b89-41ba1a2549d4' User entered 'No (N)'	System	09 Sep 2020 07:04:52
	System	09 Sep 2020 07:04:52

US3732023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:28:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-09T00:04:49', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '1f0b7f35-1eb8-424f-9b89-41ba1a2549d4' User entered '09 Sep 2020 00:04'	System	09 Sep 2020 07:04:52
	System	09 Sep 2020 07:04:52



US3732023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:28:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 18:28:43

US3732023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:28:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 18:28:43

US3732023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
Data entry locked.	System	04 Sep 2020 18:28:43
User entered 'Day 6'	System	04 Sep 2020 18:28:43

US3732023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:28:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-09T21:55:44', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '892a5ead-15a7-49a7-a81e-e819917bfff1' User entered 'Yes (Y)'	System	10 Sep 2020 04:56:01
	System	10 Sep 2020 04:56:01

US3732023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:28:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-09T21:55:51', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '892a5ead-15a7-49a7-a81e-e819917bfff1' User entered '97.7'	System	10 Sep 2020 04:56:01
	System	10 Sep 2020 04:56:01

US3732023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-09T21:55:56', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '892a5ead-15a7-49a7-a81e-e819917bfff1' User entered 'No (N)'	System	10 Sep 2020 04:56:01
	System	10 Sep 2020 04:56:01

US3732023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:28:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-09T21:55:59', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '892a5ead-15a7-49a7-a81e-e819917bfff1' User entered '09 Sep 2020 21:55'	System	10 Sep 2020 04:56:01
	System	10 Sep 2020 04:56:01

US3732023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:28:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 18:28:43



US3732023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:28:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 18:28:43

US3732023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
Data entry locked.	System	04 Sep 2020 18:28:43
User entered 'Day 7'	System	04 Sep 2020 18:28:43

US3732023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:28:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-10T20:00:06', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '2362eff0-5c28-408b-a7fc-377e858e18e4' User entered 'Yes (Y)'	System	11 Sep 2020 03:00:45
	System	11 Sep 2020 03:00:45

US3732023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:28:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-10T20:00:35', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '2362eff0-5c28-408b-a7fc-377e858e18e4' User entered '98.3'	System	11 Sep 2020 03:00:45
	System	11 Sep 2020 03:00:45

US3732023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-10T20:00:39', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '2362eff0-5c28-408b-a7fc-377e858e18e4'	System	11 Sep 2020 03:00:45
User entered 'No (N)'	System	11 Sep 2020 03:00:45

US3732023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:28:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-10T20:00:43', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '2362eff0-5c28-408b-a7fc-377e858e18e4' User entered '10 Sep 2020 20:00'	System	11 Sep 2020 03:00:45
	System	11 Sep 2020 03:00:45

US3732023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:28:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 18:28:43

US3732023

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:28:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 18:28:43



US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
Data entry locked.	System	04 Sep 2020 18:28:43
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 18:28:43

US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:28:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-04T12:01:41', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'cb871527-423d-4f4c-a026-7cc42dbc6bb8' User entered 'None (1)'	System	04 Sep 2020 19:02:03
	System	04 Sep 2020 19:02:03

US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:28:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-04T12:01:45', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'cb871527-423d-4f4c-a026-7cc42dbc6bb8' User entered 'No (N)'	System	04 Sep 2020 19:02:03
	System	04 Sep 2020 19:02:03

US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-04T12:01:50', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'cb871527-423d-4f4c-a026-7cc42dbc6bb8' User entered 'No (N)'	System	04 Sep 2020 19:02:03
	System	04 Sep 2020 19:02:03

US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:28:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-04T12:01:55', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'cb871527-423d-4f4c-a026-7cc42dbc6bb8' User entered 'None (1)'	System	04 Sep 2020 19:02:03
	System	04 Sep 2020 19:02:03

US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:28:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-04T12:01:59', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'cb871527-423d-4f4c-a026-7cc42dbc6bb8' User entered '04 Sep 2020 12:01'	System	04 Sep 2020 19:02:03
	System	04 Sep 2020 19:02:03

US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:28:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '04 Sep 2020 11:45'	System	04 Sep 2020 18:28:43

US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:28:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '04 Sep 2020 14:15'	System	04 Sep 2020 18:28:43



US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
Data entry locked.	System	04 Sep 2020 18:28:43
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 18:28:43

US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:28:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-04T21:20:30', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'd50d7022-af96-4a52-bb13-b9e2e9a4d1f2'	System	05 Sep 2020 04:20:50
User entered 'Does not interfere with activity (2)'	System	05 Sep 2020 04:20:50

US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:28:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-04T21:20:34', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'd50d7022-af96-4a52-bb13-b9e2e9a4d1f2'	System	05 Sep 2020 04:20:50
User entered 'No (N)'	System	05 Sep 2020 04:20:50

US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-04T21:20:38', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'd50d7022-af96-4a52-bb13-b9e2e9a4d1f2'	System	05 Sep 2020 04:20:50
User entered 'No (N)'	System	05 Sep 2020 04:20:50

US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:28:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-04T21:20:41', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'd50d7022-af96-4a52-bb13-b9e2e9a4d1f2'	System	05 Sep 2020 04:20:50
User entered 'None (1)'	System	05 Sep 2020 04:20:50

US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:28:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-04T21:20:49', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'd50d7022-af96-4a52-bb13-b9e2e9a4d1f2'	System	05 Sep 2020 04:20:50
User entered '04 Sep 2020 21:20'	System	05 Sep 2020 04:20:50

US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:28:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '04 Sep 2020 15:10'	System	04 Sep 2020 18:28:43

US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:28:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 18:28:43



US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
Data entry locked.	System	04 Sep 2020 18:28:43
User entered 'Day 2'	System	04 Sep 2020 18:28:43

US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:28:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-05T21:41:49', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '0cbb1369-2d97-4fb2-932e-4f83a1861f1b'	System	06 Sep 2020 04:42:10
User entered 'Does not interfere with activity (2)'	System	06 Sep 2020 04:42:10

US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:28:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-05T21:41:52', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '0cbb1369-2d97-4fb2-932e-4f83a1861f1b' User entered 'No (N)'	System	06 Sep 2020 04:42:10
	System	06 Sep 2020 04:42:10

US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-05T21:41:57', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '0cbb1369-2d97-4fb2-932e-4f83a1861f1b' User entered 'No (N)'	System	06 Sep 2020 04:42:10
	System	06 Sep 2020 04:42:10

US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:28:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-05T21:42:00', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '0cbb1369-2d97-4fb2-932e-4f83a1861f1b' User entered 'None (1)'	System	06 Sep 2020 04:42:10
	System	06 Sep 2020 04:42:10

US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:28:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-05T21:42:07', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '0cbb1369-2d97-4fb2-932e-4f83a1861f1b' User entered '05 Sep 2020 21:42'	System	06 Sep 2020 04:42:10
	System	06 Sep 2020 04:42:10

US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:28:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 18:28:43

US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:28:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 18:28:43



US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
Data entry locked.	System	04 Sep 2020 18:28:43
User entered 'Day 3'	System	04 Sep 2020 18:28:43

US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:28:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-06T19:49:50', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '5341d41f-ff67-4753-a91c-2c584f228c11'	System	07 Sep 2020 02:50:06
User entered 'Does not interfere with activity (2)'	System	07 Sep 2020 02:50:06

US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:28:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-06T19:49:53', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '5341d41f-ff67-4753-a91c-2c584f228c11' User entered 'No (N)'	System	07 Sep 2020 02:50:06
	System	07 Sep 2020 02:50:06

US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-06T19:49:55', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '5341d41f-ff67-4753-a91c-2c584f228c11' User entered 'No (N)'	System	07 Sep 2020 02:50:06
	System	07 Sep 2020 02:50:06

US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:28:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-06T19:49:58', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '5341d41f-ff67-4753-a91c-2c584f228c11' User entered 'None (1)'	System	07 Sep 2020 02:50:06
	System	07 Sep 2020 02:50:06

US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:28:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-06T19:50:03', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '5341d41f-ff67-4753-a91c-2c584f228c11' User entered '06 Sep 2020 19:50'	System	07 Sep 2020 02:50:06
	System	07 Sep 2020 02:50:06

US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:28:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 18:28:43

US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:28:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 18:28:43



US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
Data entry locked.	System	04 Sep 2020 18:28:43
User entered 'Day 4'	System	04 Sep 2020 18:28:43

US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:28:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-07T21:56:18', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '657ab41c-3814-48a8-bf41-2f39f50ebe26' User entered 'None (1)'	System	08 Sep 2020 04:56:33
	System	08 Sep 2020 04:56:33

US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:28:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-07T21:56:20', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '657ab41c-3814-48a8-bf41-2f39f50ebe26' User entered 'No (N)'	System	08 Sep 2020 04:56:33
	System	08 Sep 2020 04:56:33

US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-07T21:56:23', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '657ab41c-3814-48a8-bf41-2f39f50ebe26' User entered 'No (N)'	System	08 Sep 2020 04:56:33
	System	08 Sep 2020 04:56:33

US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:28:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-07T21:56:26', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '657ab41c-3814-48a8-bf41-2f39f50ebe26' User entered 'None (1)'	System	08 Sep 2020 04:56:33
	System	08 Sep 2020 04:56:33

**US3732023**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:28:58**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-07T21:56:30', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '657ab41c-3814-48a8-bf41-2f39f50ebe26' User entered '07 Sep 2020 21:56'	System	08 Sep 2020 04:56:33
	System	08 Sep 2020 04:56:33

US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:28:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 18:28:43

US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:28:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 18:28:43



US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
Data entry locked.	System	04 Sep 2020 18:28:43
User entered 'Day 5'	System	04 Sep 2020 18:28:43

US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:28:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-09T00:04:55', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '77f69673-fe16-44ff-a336-7eefa32fa8d9'	System	09 Sep 2020 07:05:11
User entered 'None (1)'	System	09 Sep 2020 07:05:11

US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:28:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-09T00:04:58', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '77f69673-fe16-44ff-a336-7eefa32fa8d9' User entered 'No (N)'	System	09 Sep 2020 07:05:11
	System	09 Sep 2020 07:05:11

US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-09T00:05:01', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '77f69673-fe16-44ff-a336-7eefa32fa8d9' User entered 'No (N)'	System	09 Sep 2020 07:05:11
	System	09 Sep 2020 07:05:11

US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:28:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-09T00:05:04', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '77f69673-fe16-44ff-a336-7eefa32fa8d9'	System	09 Sep 2020 07:05:11
User entered 'None (1)'	System	09 Sep 2020 07:05:11

US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:28:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-09T00:05:09', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '77f69673-fe16-44ff-a336-7eefa32fa8d9' User entered '09 Sep 2020 00:05'	System	09 Sep 2020 07:05:11
	System	09 Sep 2020 07:05:11

US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:28:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 18:28:43

US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:28:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 18:28:43



US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
Data entry locked.	System	04 Sep 2020 18:28:43
User entered 'Day 6'	System	04 Sep 2020 18:28:43

US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:28:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-09T21:56:04', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '66d3c5c8-e773-4038-9b7d-db9ee6dc7796' User entered 'None (1)'	System	10 Sep 2020 04:56:32
	System	10 Sep 2020 04:56:32

US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:28:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-09T21:56:16', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '66d3c5c8-e773-4038-9b7d-db9ee6dc7796' User entered 'No (N)'	System	10 Sep 2020 04:56:32
	System	10 Sep 2020 04:56:32

US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-09T21:56:20', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '66d3c5c8-e773-4038-9b7d-db9ee6dc7796' User entered 'No (N)'	System	10 Sep 2020 04:56:32
	System	10 Sep 2020 04:56:32

US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:28:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-09T21:56:23', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '66d3c5c8-e773-4038-9b7d-db9ee6dc7796' User entered 'None (1)'	System	10 Sep 2020 04:56:32
	System	10 Sep 2020 04:56:32

US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:28:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-09T21:56:30', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '66d3c5c8-e773-4038-9b7d-db9ee6dc7796' User entered '09 Sep 2020 21:56'	System	10 Sep 2020 04:56:32
	System	10 Sep 2020 04:56:32

US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:28:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 18:28:43

US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:28:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 18:28:43



US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
Data entry locked.	System	04 Sep 2020 18:28:43
User entered 'Day 7'	System	04 Sep 2020 18:28:43

US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:28:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-10T20:00:48', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'a0d1a2c6-259b-4151-a0ae-a81b70cbc6cb' User entered 'None (1)'	System	11 Sep 2020 03:01:04
	System	11 Sep 2020 03:01:04

US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:28:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-10T20:00:52', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'a0d1a2c6-259b-4151-a0ae-a81b70cbc6cb' User entered 'No (N)'	System	11 Sep 2020 03:01:04
	System	11 Sep 2020 03:01:04

US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-10T20:00:54', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'a0d1a2c6-259b-4151-a0ae-a81b70cbc6cb' User entered 'No (N)'	System	11 Sep 2020 03:01:04
	System	11 Sep 2020 03:01:04

US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:28:58

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-10T20:00:57', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'a0d1a2c6-259b-4151-a0ae-a81b70cbc6cb' User entered 'None (1)'	System	11 Sep 2020 03:01:04
	System	11 Sep 2020 03:01:04

US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:28:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-10T20:01:01', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'a0d1a2c6-259b-4151-a0ae-a81b70cbc6cb' User entered '10 Sep 2020 20:01'	System	11 Sep 2020 03:01:04
	System	11 Sep 2020 03:01:04

US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:28:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 18:28:43

US3732023

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:28:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 18:28:43



US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
Data entry locked.	System	04 Sep 2020 18:28:43
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 18:28:43

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:58

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-04T12:02:05', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'a956796a-b938-4ff8-9a5a-f8d8935e66bf' User entered 'None (0)'	System	04 Sep 2020 19:02:39
	System	04 Sep 2020 19:02:39

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:58

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-04T12:02:08', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'a956796a-b938-4ff8-9a5a-f8d8935e66bf' User entered 'None (0)'	System	04 Sep 2020 19:02:39
	System	04 Sep 2020 19:02:39

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-04T12:02:11', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'a956796a-b938-4ff8-9a5a-f8d8935e66bf' User entered 'None (0)'	System	04 Sep 2020 19:02:39
	System	04 Sep 2020 19:02:39

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-04T12:02:15', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'a956796a-b938-4ff8-9a5a-f8d8935e66bf' User entered 'None (0)'	System	04 Sep 2020 19:02:39
	System	04 Sep 2020 19:02:39

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:58

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-04T12:02:18', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'a956796a-b938-4ff8-9a5a-f8d8935e66bf' User entered 'None (0)'	System	04 Sep 2020 19:02:39
	System	04 Sep 2020 19:02:39

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:58

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-04T12:02:21', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'a956796a-b938-4ff8-9a5a-f8d8935e66bf' User entered 'None (0)'	System	04 Sep 2020 19:02:39
	System	04 Sep 2020 19:02:39

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:58

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)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-04T12:02:27', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'a956796a-b938-4ff8-9a5a-f8d8935e66bf' User entered 'No (N)'	System	04 Sep 2020 19:02:39
	System	04 Sep 2020 19:02:39



**US3732023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:28:58**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-04T12:02:36', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'a956796a-b938-4ff8-9a5a-f8d8935e66bf' User entered '04 Sep 2020 12:02'	System	04 Sep 2020 19:02:39
	System	04 Sep 2020 19:02:39

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '04 Sep 2020 11:45'	System	04 Sep 2020 18:28:43

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:28:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '04 Sep 2020 14:15'	System	04 Sep 2020 18:28:43

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
Data entry locked.	System	04 Sep 2020 18:28:43
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 18:28:43

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:58

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-04T21:20:55', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '0b452e72-88cb-4cb4-8ba5-b30f7a31d06d' User entered 'None (0)'	System	05 Sep 2020 04:21:26
	System	05 Sep 2020 04:21:26

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:58

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-04T21:20:58', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '0b452e72-88cb-4cb4-8ba5-b30f7a31d06d' User entered 'None (0)'	System	05 Sep 2020 04:21:26
	System	05 Sep 2020 04:21:26

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-04T21:21:01', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '0b452e72-88cb-4cb4-8ba5-b30f7a31d06d' User entered 'None (0)'	System	05 Sep 2020 04:21:26
	System	05 Sep 2020 04:21:26

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-04T21:21:04', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '0b452e72-88cb-4cb4-8ba5-b30f7a31d06d' User entered 'None (0)'	System	05 Sep 2020 04:21:26
	System	05 Sep 2020 04:21:26



US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:58

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-04T21:21:07', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '0b452e72-88cb-4cb4-8ba5-b30f7a31d06d' User entered 'None (0)'	System	05 Sep 2020 04:21:26
	System	05 Sep 2020 04:21:26

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:58

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-04T21:21:10', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '0b452e72-88cb-4cb4-8ba5-b30f7a31d06d' User entered 'None (0)'	System	05 Sep 2020 04:21:26
	System	05 Sep 2020 04:21:26

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:58

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)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-04T21:21:15', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '0b452e72-88cb-4cb4-8ba5-b30f7a31d06d' User entered 'No (N)'	System	05 Sep 2020 04:21:26
	System	05 Sep 2020 04:21:26

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-04T21:21:22', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '0b452e72-88cb-4cb4-8ba5-b30f7a31d06d' User entered '04 Sep 2020 21:21'	System	05 Sep 2020 04:21:26
	System	05 Sep 2020 04:21:26

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '04 Sep 2020 15:10'	System	04 Sep 2020 18:28:43

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:28:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 18:28:43

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
Data entry locked.	System	04 Sep 2020 18:28:43
User entered 'Day 2'	System	04 Sep 2020 18:28:43

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:58

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-05T21:42:17', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'b0bc9c8c-0651-4029-8e12-2541b6779b20'	System	06 Sep 2020 04:45:38
User entered 'No interference with activity (1)'	System	06 Sep 2020 04:45:38



US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:58

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-05T21:42:25', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'b0bc9c8c-0651-4029-8e12-2541b6779b20'	System	06 Sep 2020 04:45:38
User entered 'Some interference with activity (2)'	System	06 Sep 2020 04:45:38

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-05T21:42:31', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'b0bc9c8c-0651-4029-8e12-2541b6779b20'	System	06 Sep 2020 04:45:38
User entered 'Some interference with activity (2)'	System	06 Sep 2020 04:45:38

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-05T21:42:35', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'b0bc9c8c-0651-4029-8e12-2541b6779b20'	System	06 Sep 2020 04:45:38
User entered 'Some interference with activity (2)'	System	06 Sep 2020 04:45:38

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:58

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-05T21:42:53', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'b0bc9c8c-0651-4029-8e12-2541b6779b20'	System	06 Sep 2020 04:45:38
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	06 Sep 2020 04:45:38

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:58

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-05T21:43:01', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'b0bc9c8c-0651-4029-8e12-2541b6779b20'	System	06 Sep 2020 04:45:38
User entered 'Some interference with activity not requiring medical attention (2)'	System	06 Sep 2020 04:45:38

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:58

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)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-05T21:43:10', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'b0bc9c8c-0651-4029-8e12-2541b6779b20'	System	06 Sep 2020 04:45:38
User entered 'No (N)'	System	06 Sep 2020 04:45:38

**US3732023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:28:58**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-05T21:45:36', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'b0bc9c8c-0651-4029-8e12-2541b6779b20'	System	06 Sep 2020 04:45:38
User entered '05 Sep 2020 21:45'	System	06 Sep 2020 04:45:38

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 18:28:43



US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:28:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 18:28:43

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
Data entry locked.	System	04 Sep 2020 18:28:43
User entered 'Day 3'	System	04 Sep 2020 18:28:43

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:58

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-06T19:50:38', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '943a414e-2297-47bf-9ac5-3b00e2e89102' User entered 'None (0)'	System	07 Sep 2020 02:51:15
	System	07 Sep 2020 02:51:15

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:58

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-06T19:50:35', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '943a414e-2297-47bf-9ac5-3b00e2e89102'	System	07 Sep 2020 02:51:15
User entered 'No interference with activity (1)'	System	07 Sep 2020 02:51:15

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-06T19:51:03', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '943a414e-2297-47bf-9ac5-3b00e2e89102' User entered 'None (0)'	System	07 Sep 2020 02:51:15
	System	07 Sep 2020 02:51:15

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-06T19:50:44', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '943a414e-2297-47bf-9ac5-3b00e2e89102' User entered 'None (0)'	System	07 Sep 2020 02:51:15
	System	07 Sep 2020 02:51:15

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:58

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-06T19:50:46', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '943a414e-2297-47bf-9ac5-3b00e2e89102' User entered 'None (0)'	System	07 Sep 2020 02:51:15
	System	07 Sep 2020 02:51:15

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:58

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-06T19:50:48', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '943a414e-2297-47bf-9ac5-3b00e2e89102' User entered 'None (0)'	System	07 Sep 2020 02:51:15
	System	07 Sep 2020 02:51:15



US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:58

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)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-06T19:50:51', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '943a414e-2297-47bf-9ac5-3b00e2e89102'	System	07 Sep 2020 02:51:15
User entered 'No (N)'	System	07 Sep 2020 02:51:15

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-06T19:51:12', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '943a414e-2297-47bf-9ac5-3b00e2e89102' User entered '06 Sep 2020 19:51'	System	07 Sep 2020 02:51:15
	System	07 Sep 2020 02:51:15

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 18:28:43

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:28:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 18:28:43

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
Data entry locked.	System	04 Sep 2020 18:28:43
User entered 'Day 4'	System	04 Sep 2020 18:28:43

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:58

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-07T21:56:35', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'f116fdab-f803-4c19-a370-6a794cb5d7d8' User entered 'None (0)'	System	08 Sep 2020 04:57:00
	System	08 Sep 2020 04:57:00

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:58

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-07T21:56:38', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'f116fdab-f803-4c19-a370-6a794cb5d7d8' User entered 'None (0)'	System	08 Sep 2020 04:57:00
	System	08 Sep 2020 04:57:00

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-07T21:56:41', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'f116fdab-f803-4c19-a370-6a794cb5d7d8' User entered 'None (0)'	System	08 Sep 2020 04:57:00
	System	08 Sep 2020 04:57:00



US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-07T21:56:43', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'f116fdab-f803-4c19-a370-6a794cb5d7d8' User entered 'None (0)'	System	08 Sep 2020 04:57:00
	System	08 Sep 2020 04:57:00

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:58

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-07T21:56:46', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'f116fdab-f803-4c19-a370-6a794cb5d7d8' User entered 'None (0)'	System	08 Sep 2020 04:57:00
	System	08 Sep 2020 04:57:00

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:58

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-07T21:56:49', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'f116fdab-f803-4c19-a370-6a794cb5d7d8' User entered 'None (0)'	System	08 Sep 2020 04:57:00
	System	08 Sep 2020 04:57:00

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:58

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)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-07T21:56:52', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'f116fdab-f803-4c19-a370-6a794cb5d7d8' User entered 'No (N)'	System	08 Sep 2020 04:57:00
	System	08 Sep 2020 04:57:00

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-07T21:56:58', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'f116fdab-f803-4c19-a370-6a794cb5d7d8' User entered '07 Sep 2020 21:56'	System	08 Sep 2020 04:57:00
	System	08 Sep 2020 04:57:00

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 18:28:43

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:28:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 18:28:43

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
Data entry locked.	System	04 Sep 2020 18:28:43
User entered 'Day 5'	System	04 Sep 2020 18:28:43



US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:58

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-09T00:05:15', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '0c1a4c7a-e4d2-45fe-98ac-a98bfd888490' User entered 'None (0)'	System	09 Sep 2020 07:05:41
	System	09 Sep 2020 07:05:41

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:58

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-09T00:05:17', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '0c1a4c7a-e4d2-45fe-98ac-a98bfd888490' User entered 'None (0)'	System	09 Sep 2020 07:05:41
	System	09 Sep 2020 07:05:41

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-09T00:05:20', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '0c1a4c7a-e4d2-45fe-98ac-a98bfd888490' User entered 'None (0)'	System	09 Sep 2020 07:05:41
	System	09 Sep 2020 07:05:41

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-09T00:05:22', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '0c1a4c7a-e4d2-45fe-98ac-a98bfd888490' User entered 'None (0)'	System	09 Sep 2020 07:05:41
	System	09 Sep 2020 07:05:41

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:58

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-09T00:05:24', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '0c1a4c7a-e4d2-45fe-98ac-a98bfd888490' User entered 'None (0)'	System	09 Sep 2020 07:05:41
	System	09 Sep 2020 07:05:41

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:58

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-09T00:05:27', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '0c1a4c7a-e4d2-45fe-98ac-a98bfd888490' User entered 'None (0)'	System	09 Sep 2020 07:05:41
	System	09 Sep 2020 07:05:41

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:58

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)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-09T00:05:30', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '0c1a4c7a-e4d2-45fe-98ac-a98bfd888490' User entered 'No (N)'	System	09 Sep 2020 07:05:41
	System	09 Sep 2020 07:05:41

**US3732023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:28:58**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-09T00:05:38', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '0c1a4c7a-e4d2-45fe-98ac-a98bfd888490' User entered '09 Sep 2020 00:05'	System	09 Sep 2020 07:05:41
	System	09 Sep 2020 07:05:41



US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 18:28:43

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:28:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 18:28:43

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
Data entry locked.	System	04 Sep 2020 18:28:43
User entered 'Day 6'	System	04 Sep 2020 18:28:43

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:58

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-09T21:56:35', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'e5040d00-a1a6-4885-8107-591a00411279' User entered 'None (0)'	System	10 Sep 2020 04:57:03
	System	10 Sep 2020 04:57:03

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:58

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-09T21:56:37', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'e5040d00-a1a6-4885-8107-591a00411279' User entered 'None (0)'	System	10 Sep 2020 04:57:03
	System	10 Sep 2020 04:57:03

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-09T21:56:40', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'e5040d00-a1a6-4885-8107-591a00411279' User entered 'None (0)'	System	10 Sep 2020 04:57:03
	System	10 Sep 2020 04:57:03

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-09T21:56:43', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'e5040d00-a1a6-4885-8107-591a00411279' User entered 'None (0)'	System	10 Sep 2020 04:57:03
	System	10 Sep 2020 04:57:03

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:58

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-09T21:56:46', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'e5040d00-a1a6-4885-8107-591a00411279' User entered 'None (0)'	System	10 Sep 2020 04:57:03
	System	10 Sep 2020 04:57:03



US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:58

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-09T21:56:48', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'e5040d00-a1a6-4885-8107-591a00411279' User entered 'None (0)'	System	10 Sep 2020 04:57:03
	System	10 Sep 2020 04:57:03

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:58

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)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-09T21:56:51', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'e5040d00-a1a6-4885-8107-591a00411279' User entered 'No (N)'	System	10 Sep 2020 04:57:03
	System	10 Sep 2020 04:57:03

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-09T21:56:59', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'e5040d00-a1a6-4885-8107-591a00411279' User entered '09 Sep 2020 21:56'	System	10 Sep 2020 04:57:03
	System	10 Sep 2020 04:57:03

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 18:28:43

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:28:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 18:28:43

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
Data entry locked.	System	04 Sep 2020 18:28:43
User entered 'Day 7'	System	04 Sep 2020 18:28:43

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:58

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-10T20:01:06', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '32ea25ba-27f4-4299-ac0e-ef071850cdab' User entered 'None (0)'	System	11 Sep 2020 03:01:28
	System	11 Sep 2020 03:01:28

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:58

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-10T20:01:09', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '32ea25ba-27f4-4299-ac0e-ef071850cdab' User entered 'None (0)'	System	11 Sep 2020 03:01:28
	System	11 Sep 2020 03:01:28



US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:58

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-10T20:01:11', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '32ea25ba-27f4-4299-ac0e-ef071850cdab' User entered 'None (0)'	System	11 Sep 2020 03:01:28
	System	11 Sep 2020 03:01:28

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:58

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-10T20:01:13', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '32ea25ba-27f4-4299-ac0e-ef071850cdab' User entered 'None (0)'	System	11 Sep 2020 03:01:28
	System	11 Sep 2020 03:01:28

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:58

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-10T20:01:15', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '32ea25ba-27f4-4299-ac0e-ef071850cdab' User entered 'None (0)'	System	11 Sep 2020 03:01:28
	System	11 Sep 2020 03:01:28

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:58

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-10T20:01:17', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '32ea25ba-27f4-4299-ac0e-ef071850cdab' User entered 'None (0)'	System	11 Sep 2020 03:01:28
	System	11 Sep 2020 03:01:28

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:58

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)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-10T20:01:20', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '32ea25ba-27f4-4299-ac0e-ef071850cdab' User entered 'No (N)'	System	11 Sep 2020 03:01:28
	System	11 Sep 2020 03:01:28

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-09-10T20:01:26', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '32ea25ba-27f4-4299-ac0e-ef071850cdab' User entered '10 Sep 2020 20:01'	System	11 Sep 2020 03:01:28
	System	11 Sep 2020 03:01:28

**US3732023**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:28:58**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 18:28:43

US3732023

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:28:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 18:28:43



US3732023

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'Yes (Y)'	Linda Vega (b) (4)	14 Sep 2020 19:14:14

US3732023

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:58

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered '14 Sep 2020'	Linda Vega (b) (4)	14 Sep 2020 19:14:14

US3732023

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'Contact Made (CONTACT MADE)'	Linda Vega (b) (4)	14 Sep 2020 19:14:14

US3732023

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:58

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered empty.	Linda Vega (b) (4)	14 Sep 2020 19:14:14

US3732023

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:28:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'Yes (Y)'	Linda Vega (b) (4)	14 Sep 2020 19:14:20

US3732023

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:28:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User entered '1'	System	14 Sep 2020 19:14:20

**US3732023**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:28:58**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'Yes (Y)'	Linda Vega (b) (4)	18 Sep 2020 22:34:53

US3732023

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:58

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered '18 Sep 2020'	Linda Vega (b) (4)	18 Sep 2020 22:34:53



US3732023

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'Contact Made (CONTACT MADE)'	Linda Vega (b) (4)	18 Sep 2020 22:34:53

US3732023

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:58

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered empty.	Linda Vega (b) (4)	18 Sep 2020 22:34:53

US3732023

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:28:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'Yes (Y)'	Linda Vega (b) (4)	18 Sep 2020 22:34:56

**US3732023**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:28:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User entered '1'	System	18 Sep 2020 22:34:56

US3732023

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'Yes (Y)'	Linda Vega (b) (4)	25 Sep 2020 20:30:45

US3732023

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:58

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered '25 Sep 2020'	Linda Vega (b) (4)	25 Sep 2020 20:30:45

US3732023

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'Contact Made (CONTACT MADE)'	Linda Vega (b) (4)	25 Sep 2020 20:30:45

US3732023

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:58

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered empty.	Linda Vega (b) (4)	25 Sep 2020 20:30:45



US3732023

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:28:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'Yes (Y)'	Linda Vega (b) (4)	25 Sep 2020 20:30:48

**US3732023**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:28:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User entered 'I'	System	25 Sep 2020 20:30:48

US3732023

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:28:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:14
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	02 Oct 2020 19:50:01

US3732023

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:14
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '02 Oct 2020'	Lauren Arnett (b) (4)	02 Oct 2020 19:50:01

US3732023

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:28:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:14
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'Clinic (Clinic)'	Lauren Arnett (b) (4)	02 Oct 2020 19:50:01

**US3732023**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:28:58**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:14
User entered 'VISIT3'	System	02 Oct 2020 19:50:01

US3732023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:14
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	02 Oct 2020 19:50:36

US3732023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:14
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '02 Oct 2020'	Lauren Arnett (b) (4)	02 Oct 2020 19:50:36



US3732023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:58

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:14
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '11:10'	Lauren Arnett (b) (4)	02 Oct 2020 19:50:36

US3732023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:58

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:14
User entered '02 Oct 2020 11:10'	System	02 Oct 2020 19:50:36

US3732023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:14
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '98.1' F	Lauren Arnett (b) (4)	02 Oct 2020 19:50:36

US3732023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:14
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'Oral (Oral)'	Lauren Arnett (b) (4)	02 Oct 2020 19:50:36

US3732023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:14
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered empty.	Lauren Arnett (b) (4)	02 Oct 2020 19:50:36

US3732023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:14
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '65'	Lauren Arnett (b) (4)	02 Oct 2020 19:50:36

US3732023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:14
User entered 'bpm'	System	02 Oct 2020 19:50:36

US3732023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:14
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '16'	Lauren Arnett (b) (4)	02 Oct 2020 19:50:36



US3732023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:14
User entered 'breaths/min'	System	02 Oct 2020 19:50:36

US3732023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:14
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '109'	Lauren Arnett (b) (4)	02 Oct 2020 19:50:36

US3732023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:14
User entered 'mmHg'	System	02 Oct 2020 19:50:36

US3732023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:14
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '60'	Lauren Arnett (b) (4)	02 Oct 2020 19:50:36

US3732023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:58

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:14
User entered 'mmHg'	System	02 Oct 2020 19:50:36

US3732023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:58

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:14

US3732023

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:58

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:14

US3732023

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:28:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:14
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	02 Oct 2020 19:50:46



US3732023

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:28:58

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:14
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '02 Oct 2020'	Lauren Arnett (b) (4)	02 Oct 2020 19:50:46

US3732023

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:28:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:14
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	02 Oct 2020 19:50:59

US3732023

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:28:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:14
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '02 Oct 2020'	Lauren Arnett (b) (4)	02 Oct 2020 19:50:59

US3732023

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:28:58

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:14
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered '11:27'	Lauren Arnett (b) (4)	02 Oct 2020 19:50:59

**US3732023**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:28:58**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:14
User entered '02 Oct 2020 11:27'	System	02 Oct 2020 19:50:59

US3732023

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:28:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:14
User signature succeeded.	Scott Overcash (b) (4)	24 Feb 2021 21:53:53
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	02 Oct 2020 19:51:03

US3732023

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:28:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:14
User entered 'I'	System	02 Oct 2020 19:51:03

US3732023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
Data entry locked.	System	07 Aug 2020 19:08:58
User entered 'Day 64'	System	07 Aug 2020 19:08:58



US3732023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

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 Feb 2021 19:58:30
User closed query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 18:32:28
Query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'AE opened' (Site from DM).	Lauren Arnett (b) (4) (b) (4)	06 Nov 2020 19:37:49
User opened query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	31 Oct 2020 06:43:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-10-07T19:42:11', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'c4125a6f-ca59-4978-b805-30bad22465bc'	System	08 Oct 2020 02:42:57
User entered 'Yes (Y)'	System	08 Oct 2020 02:42:57

US3732023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

Have you been exposed to someone with 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 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-10-07T19:42:17', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'c4125a6f-ca59-4978-b805-30bad22465bc' User entered 'No (N)'	System	08 Oct 2020 02:42:57
	System	08 Oct 2020 02:42:57

US3732023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

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 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-10-07T19:42:23', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'c4125a6f-ca59-4978-b805-30bad22465bc' User entered 'No (N)'	System	08 Oct 2020 02:42:57
	System	08 Oct 2020 02:42:57

US3732023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

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 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-10-07T19:42:32', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'c4125a6f-ca59-4978-b805-30bad22465bc' User entered 'Yes (Y)'	System	08 Oct 2020 02:42:57
	System	08 Oct 2020 02:42:57

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Please 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 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-10-07T19:42:41', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'c4125a6f-ca59-4978-b805-30bad22465bc'	System	08 Oct 2020 02:42:57
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	08 Oct 2020 02:42:57

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-10-07T19:42:49', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'c4125a6f-ca59-4978-b805-30bad22465bc' User entered '07 Oct 2020 19:42:49'	System	08 Oct 2020 02:42:57
	System	08 Oct 2020 02:42:57

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
Data entry locked.	System	07 Aug 2020 19:08:58
User entered '07 Oct 2020 00:01'	System	07 Aug 2020 19:08:58

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
Data entry locked.	System	07 Aug 2020 19:08:58
User entered '11 Oct 2020 23:59'	System	07 Aug 2020 19:08:58



US3732023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
Data entry locked.	System	07 Aug 2020 19:08:58
User entered 'Day 71'	System	07 Aug 2020 19:08:58

US3732023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

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 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-10-15T13:52:28', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'a0c0530b-4669-4450-8262-696b3a895024'	System	15 Oct 2020 20:52:47
User entered 'No (N)'	System	15 Oct 2020 20:52:47

US3732023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

Have you been exposed to someone with 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 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-10-15T13:52:37', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'a0c0530b-4669-4450-8262-696b3a895024'	System	15 Oct 2020 20:52:47
User entered 'No (N)'	System	15 Oct 2020 20:52:47

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-10-15T13:52:43', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'a0c0530b-4669-4450-8262-696b3a895024' User entered '15 Oct 2020 13:52:43'	System	15 Oct 2020 20:52:47
	System	15 Oct 2020 20:52:47

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
Data entry locked.	System	07 Aug 2020 19:08:58
User entered '14 Oct 2020 00:01'	System	07 Aug 2020 19:08:58

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
Data entry locked.	System	07 Aug 2020 19:08:58
User entered '18 Oct 2020 23:59'	System	07 Aug 2020 19:08:58

US3732023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
Data entry locked.	System	07 Aug 2020 19:08:58
User entered 'Day 78'	System	07 Aug 2020 19:08:58

US3732023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

[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 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-10-22T21:25:46', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'dbd29a21-dc72-47ca-a01d-12a7cb62f45d' User entered 'No (N)'	System	23 Oct 2020 04:26:02
	System	23 Oct 2020 04:26:02



US3732023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

Have you been exposed to someone with 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 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-10-22T21:25:52', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'dbd29a21-dc72-47ca-a01d-12a7cb62f45d'	System	23 Oct 2020 04:26:02
User entered 'No (N)'	System	23 Oct 2020 04:26:02

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-10-22T21:25:58', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'dbd29a21-dc72-47ca-a01d-12a7cb62f45d' User entered '22 Oct 2020 21:25:58'	System	23 Oct 2020 04:26:02
	System	23 Oct 2020 04:26:02

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
Data entry locked.	System	07 Aug 2020 19:08:58
User entered '21 Oct 2020 00:01'	System	07 Aug 2020 19:08:58

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
Data entry locked.	System	07 Aug 2020 19:08:58
User entered '25 Oct 2020 23:59'	System	07 Aug 2020 19:08:58

US3732023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
Data entry locked.	System	07 Aug 2020 19:08:58
User entered 'Day 92'	System	07 Aug 2020 19:08:58

US3732023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

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 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-11-06T07:13:47', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '45cfb877-2a77-4c58-bb79-c57c42357e79' User entered 'No (N)'	System	06 Nov 2020 15:14:04
	System	06 Nov 2020 15:14:04

US3732023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

Have you been exposed to someone with 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 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-11-06T07:13:55', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '45cfb877-2a77-4c58-bb79-c57c42357e79'	System	06 Nov 2020 15:14:04
User entered 'No (N)'	System	06 Nov 2020 15:14:04

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-11-06T07:14:01', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '45cfb877-2a77-4c58-bb79-c57c42357e79' User entered '06 Nov 2020 07:14:01'	System	06 Nov 2020 15:14:04
	System	06 Nov 2020 15:14:04



**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
Data entry locked.	System	07 Aug 2020 19:08:58
User entered '04 Nov 2020 00:01'	System	07 Aug 2020 19:08:58

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
Data entry locked.	System	07 Aug 2020 19:08:58
User entered '08 Nov 2020 23:59'	System	07 Aug 2020 19:08:58

US3732023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
Data entry locked.	System	07 Aug 2020 19:08:58
User entered 'Day 99'	System	07 Aug 2020 19:08:58

US3732023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

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 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-11-11T20:27:19', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'e00d3ac9-14dc-4dbf-b8b8-1ded5d147079'	System	12 Nov 2020 04:27:46
User entered 'No (N)'	System	12 Nov 2020 04:27:46

US3732023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

Have you been exposed to someone with 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 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-11-11T20:27:30', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'e00d3ac9-14dc-4dbf-b8b8-1ded5d147079'	System	12 Nov 2020 04:27:46
User entered 'No (N)'	System	12 Nov 2020 04:27:46

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-11-11T20:27:40', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'e00d3ac9-14dc-4dbf-b8b8-1ded5d147079' User entered '11 Nov 2020 20:27:40'	System	12 Nov 2020 04:27:46
	System	12 Nov 2020 04:27:46

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
Data entry locked.	System	07 Aug 2020 19:08:58
User entered '11 Nov 2020 00:01'	System	07 Aug 2020 19:08:58

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
Data entry locked.	System	07 Aug 2020 19:08:58
User entered '15 Nov 2020 23:59'	System	07 Aug 2020 19:08:58



US3732023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
Data entry locked.	System	07 Aug 2020 19:08:58
User entered 'Day 106'	System	07 Aug 2020 19:08:58

US3732023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

[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 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-11-19T06:49:07', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '941a7894-0932-4ad7-badf-c7373a9fd671' User entered 'No (N)'	System	19 Nov 2020 14:49:20
	System	19 Nov 2020 14:49:20

US3732023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

Have you been exposed to someone with 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 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-11-19T06:49:12', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '941a7894-0932-4ad7-badf-c7373a9fd671'	System	19 Nov 2020 14:49:20
User entered 'No (N)'	System	19 Nov 2020 14:49:20

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-11-19T06:49:15', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '941a7894-0932-4ad7-badf-c7373a9fd671' User entered '19 Nov 2020 06:49:15'	System	19 Nov 2020 14:49:20
	System	19 Nov 2020 14:49:20

US3732023

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:28:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
Data entry locked.	System	07 Aug 2020 19:08:58
User entered '18 Nov 2020 00:01'	System	07 Aug 2020 19:08:58

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 19:58:30
Data entry locked.	System	07 Aug 2020 19:08:58
User entered '22 Nov 2020 23:59'	System	07 Aug 2020 19:08:58

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 16:08:58

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 16:08:58



**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 16:08:58

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[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 (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-11-29T07:14:51', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'b4dd205f-542c-4d82-bb53-40c7435dd483'	System	29 Nov 2020 15:15:05
User entered 'No (N)'	System	29 Nov 2020 15:15:05

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

Have you been exposed to someone with 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 (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-11-29T07:14:57', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'b4dd205f-542c-4d82-bb53-40c7435dd483'	System	29 Nov 2020 15:15:05
User entered 'No (N)'	System	29 Nov 2020 15:15:05

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-11-29T07:15:03', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'b4dd205f-542c-4d82-bb53-40c7435dd483' User entered '29 Nov 2020 07:15:03'	System	29 Nov 2020 15:15:05
	System	29 Nov 2020 15:15:05

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 16:08:58



**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[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 (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-12-06T22:09:24', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '4528cd9b-9fb0-469a-9720-de506bef1412'	System	07 Dec 2020 06:09:35
User entered 'No (N)'	System	07 Dec 2020 06:09:35

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

Have you been exposed to someone with 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 (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-12-06T22:09:28', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '4528cd9b-9fb0-469a-9720-de506bef1412'	System	07 Dec 2020 06:09:35
User entered 'No (N)'	System	07 Dec 2020 06:09:35

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-12-06T22:09:31', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '4528cd9b-9fb0-469a-9720-de506bef1412' User entered '06 Dec 2020 22:09:31'	System	07 Dec 2020 06:09:35
	System	07 Dec 2020 06:09:35

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 16:08:58

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[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 (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-12-13T06:33:51', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'bd0bba7a-3413-4e45-b2c0-3692d73d2353'	System	13 Dec 2020 14:34:03
User entered 'No (N)'	System	13 Dec 2020 14:34:03

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

Have you been exposed to someone with 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 (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-12-13T06:33:56', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'bd0bba7a-3413-4e45-b2c0-3692d73d2353'	System	13 Dec 2020 14:34:03
User entered 'No (N)'	System	13 Dec 2020 14:34:03



**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-12-13T06:34:00', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'bd0bba7a-3413-4e45-b2c0-3692d73d2353'	System	13 Dec 2020 14:34:03
User entered '13 Dec 2020 06:34:00'	System	13 Dec 2020 14:34:03

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 16:08:58

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[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 (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-12-20T20:57:36', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'd11c5b43-0f47-47fc-b4a4-d5e99b058f48'	System	21 Dec 2020 04:57:49
User entered 'No (N)'	System	21 Dec 2020 04:57:49

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

Have you been exposed to someone with 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 (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-12-20T20:57:42', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'd11c5b43-0f47-47fc-b4a4-d5e99b058f48'	System	21 Dec 2020 04:57:49
User entered 'No (N)'	System	21 Dec 2020 04:57:49

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-12-20T20:57:46', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'd11c5b43-0f47-47fc-b4a4-d5e99b058f48' User entered '20 Dec 2020 20:57:46'	System	21 Dec 2020 04:57:49
	System	21 Dec 2020 04:57:49

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 16:08:58



**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 16:08:58

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[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 (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-12-27T22:21:23', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '127d6688-59ac-4bfd-bd9e-fb8271d5a1c1' User entered 'No (N)'	System	28 Dec 2020 06:21:34
	System	28 Dec 2020 06:21:34

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

Have you been exposed to someone with 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 (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-12-27T22:21:25', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '127d6688-59ac-4bfd-bd9e-fb8271d5a1c1' User entered 'No (N)'	System	28 Dec 2020 06:21:34

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2020-12-27T22:21:29', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '127d6688-59ac-4bfd-bd9e-fb8271d5a1c1' User entered '27 Dec 2020 22:21:29'	System	28 Dec 2020 06:21:34
	System	28 Dec 2020 06:21:34

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 16:08:58



**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[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 (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2021-01-03T00:02:09', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '67e2b58a-5132-499e-b664-ac6f342e0d6a' User entered 'No (N)'	System	03 Jan 2021 08:02:24
	System	03 Jan 2021 08:02:24

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

Have you been exposed to someone with 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 (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2021-01-03T00:02:16', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '67e2b58a-5132-499e-b664-ac6f342e0d6a' User entered 'No (N)'	System	03 Jan 2021 08:02:24
	System	03 Jan 2021 08:02:24

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2021-01-03T00:02:21', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '67e2b58a-5132-499e-b664-ac6f342e0d6a' User entered '03 Jan 2021 00:02:21'	System	03 Jan 2021 08:02:24
	System	03 Jan 2021 08:02:24

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 16:08:58

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[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 (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2021-01-10T15:33:06', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '9fa07cd4-1e83-4ad7-ba23-dccfd907d1f6'	System	10 Jan 2021 23:33:16
User entered 'No (N)'	System	10 Jan 2021 23:33:16

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

Have you been exposed to someone with 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 (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2021-01-10T15:33:09', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '9fa07cd4-1e83-4ad7-ba23-dccfd907d1f6'	System	10 Jan 2021 23:33:16
User entered 'No (N)'	System	10 Jan 2021 23:33:16



**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2021-01-10T15:33:12', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '9fa07cd4-1e83-4ad7-ba23-dccfd907d1f6' User entered '10 Jan 2021 15:33:12'	System	10 Jan 2021 23:33:16
	System	10 Jan 2021 23:33:16

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 16:08:58

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[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 (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2021-01-17T12:05:20', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '1d688fd2-aa8f-4508-8912-26374ad5ec42'	System	17 Jan 2021 20:05:29
User entered 'No (N)'	System	17 Jan 2021 20:05:29

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

Have you been exposed to someone with 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 (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2021-01-17T12:05:22', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '1d688fd2-aa8f-4508-8912-26374ad5ec42'	System	17 Jan 2021 20:05:29
User entered 'No (N)'	System	17 Jan 2021 20:05:29

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2021-01-17T12:05:26', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '1d688fd2-aa8f-4508-8912-26374ad5ec42' User entered '17 Jan 2021 12:05:26'	System	17 Jan 2021 20:05:29
	System	17 Jan 2021 20:05:29

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 16:08:58



**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 16:08:58

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[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 (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2021-01-24T14:13:57', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '9dffa2f3-54b1-4b30-9044-b520470df0e5' User entered 'No (N)'	System	24 Jan 2021 22:14:06
	System	24 Jan 2021 22:14:06

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

Have you been exposed to someone with 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 (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2021-01-24T14:13:59', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '9dffa2f3-54b1-4b30-9044-b520470df0e5'	System	24 Jan 2021 22:14:06
User entered 'No (N)'	System	24 Jan 2021 22:14:06

**US3732023**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2021-01-24T14:14:02', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '9dffa2f3-54b1-4b30-9044-b520470df0e5' User entered '24 Jan 2021 14:14:02'	System	24 Jan 2021 22:14:06
	System	24 Jan 2021 22:14:06

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 16:08:58



**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[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 (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2021-01-31T08:39:32', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'd140d31b-c557-418d-8acb-2dfb662a3ec1' User entered 'No (N)'	System	31 Jan 2021 16:40:05
	System	31 Jan 2021 16:40:05

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

Have you been exposed to someone with 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 (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2021-01-31T08:39:40', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'd140d31b-c557-418d-8acb-2dfb662a3ec1' User entered 'Yes (Y)'	System	31 Jan 2021 16:40:05
	System	31 Jan 2021 16:40:05

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2021-01-31T08:39:51', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'd140d31b-c557-418d-8acb-2dfb662a3ec1'	System	31 Jan 2021 16:40:05
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	31 Jan 2021 16:40:05

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2021-01-31T08:39:56', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'd140d31b-c557-418d-8acb-2dfb662a3ec1' User entered '31 Jan 2021 08:39:56'	System	31 Jan 2021 16:40:05
	System	31 Jan 2021 16:40:05

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[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 (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2021-02-07T09:32:18', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '3e233761-c79e-462f-8c9f-71f0988c843e' User entered 'No (N)'	System	07 Feb 2021 17:32:30
	System	07 Feb 2021 17:32:30



**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

Have you been exposed to someone with 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 (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2021-02-07T09:32:22', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '3e233761-c79e-462f-8c9f-71f0988c843e' User entered 'No (N)'	System	07 Feb 2021 17:32:30
	System	07 Feb 2021 17:32:30

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2021-02-07T09:32:25', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '3e233761-c79e-462f-8c9f-71f0988c843e' User entered '07 Feb 2021 09:32:25'	System	07 Feb 2021 17:32:30
	System	07 Feb 2021 17:32:30

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[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 (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2021-02-14T06:46:53', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '09babdc9-aba6-4e97-b354-a03ffe9a0472'	System	14 Feb 2021 14:47:02
User entered 'No (N)'	System	14 Feb 2021 14:47:02

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

Have you been exposed to someone with 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 (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2021-02-14T06:46:56', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '09babdc9-aba6-4e97-b354-a03ffe9a0472'	System	14 Feb 2021 14:47:02
User entered 'No (N)'	System	14 Feb 2021 14:47:02

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2021-02-14T06:46:59', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '09babdc9-aba6-4e97-b354-a03ffe9a0472' User entered '14 Feb 2021 06:46:59'	System	14 Feb 2021 14:47:02
	System	14 Feb 2021 14:47:02



**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[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 (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2021-02-21T08:04:30', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '04a8eaff-ae99-4851-bb7c-e047334a6053'	System	21 Feb 2021 16:04:38
User entered 'No (N)'	System	21 Feb 2021 16:04:38

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

Have you been exposed to someone with 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 (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2021-02-21T08:04:32', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '04a8eaff-ae99-4851-bb7c-e047334a6053'	System	21 Feb 2021 16:04:38
User entered 'No (N)'	System	21 Feb 2021 16:04:38

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2021-02-21T08:04:35', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '04a8eaff-ae99-4851-bb7c-e047334a6053' User entered '21 Feb 2021 08:04:35'	System	21 Feb 2021 16:04:38
	System	21 Feb 2021 16:04:38

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 16:08:58



**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[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 (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2021-02-28T05:57:17-08:00', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '45717946-d06a-4d3b-bfc0-aa6e2dfcab7a' User entered 'No (N)'	System	28 Feb 2021 13:57:34
	System	28 Feb 2021 13:57:34

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

Have you been exposed to someone with 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 (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2021-02-28T05:57:20-08:00', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '45717946-d06a-4d3b-bfc0-aa6e2dfcab7a' User entered 'No (N)'	System	28 Feb 2021 13:57:34

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2021-02-28T05:57:27-08:00', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '45717946-d06a-4d3b-bfc0-aa6e2dfcab7a' User entered '28 Feb 2021 13:57:27'	System	28 Feb 2021 13:57:34
	System	28 Feb 2021 13:57:34

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[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 (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2021-03-07T09:06:51-08:00', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'c8265625-6284-49da-be42-21983b51ef21'	System	07 Mar 2021 17:12:10
User entered 'No (N)'	System	07 Mar 2021 17:12:10



**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

Have you been exposed to someone with 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 (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2021-03-07T09:06:54-08:00', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'c8265625-6284-49da-be42-21983b51ef21'	System	07 Mar 2021 17:12:10
User entered 'No (N)'	System	07 Mar 2021 17:12:10

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2021-03-07T09:06:57-08:00', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'c8265625-6284-49da-be42-21983b51ef21'	System	07 Mar 2021 17:12:10
User entered '07 Mar 2021 09:06:57'	System	07 Mar 2021 17:12:10

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[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 (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2021-03-14T09:25:28-07:00', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '71a43d22-a3dc-4967-9076-9672f4a78201' User entered 'No (N)'	System	14 Mar 2021 16:25:38
	System	14 Mar 2021 16:25:38

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

Have you been exposed to someone with 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 (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2021-03-14T09:25:31-07:00', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '71a43d22-a3dc-4967-9076-9672f4a78201' User entered 'No (N)'	System	14 Mar 2021 16:25:38
	System	14 Mar 2021 16:25:38

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2021-03-14T09:25:35-07:00', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '71a43d22-a3dc-4967-9076-9672f4a78201' User entered '14 Mar 2021 09:25:35'	System	14 Mar 2021 16:25:38
	System	14 Mar 2021 16:25:38



**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[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 (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2021-03-22T05:39:02-07:00', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '7d61fcd8-68f6-431b-a1ad-9f25cf60b1d8'	System	22 Mar 2021 12:39:11
User entered 'No (N)'	System	22 Mar 2021 12:39:11

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

Have you been exposed to someone with 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 (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2021-03-22T05:39:04-07:00', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '7d61fcd8-68f6-431b-a1ad-9f25cf60b1d8'	System	22 Mar 2021 12:39:11
User entered 'No (N)'	System	22 Mar 2021 12:39:11

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2021-03-22T05:39:07-07:00', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '7d61fcd8-68f6-431b-a1ad-9f25cf60b1d8'	System	22 Mar 2021 12:39:11
User entered '22 Mar 2021 05:39:07'	System	22 Mar 2021 12:39:11

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 16:08:58



**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[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 (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2021-03-28T12:13:38-07:00', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'ee8ae2e3-a382-4e5c-9b5a-c93e66d8cab7'	System	28 Mar 2021 19:13:46
User entered 'No (N)'	System	28 Mar 2021 19:13:46

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

Have you been exposed to someone with 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 (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2021-03-28T12:13:40-07:00', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'ee8ae2e3-a382-4e5c-9b5a-c93e66d8cab7'	System	28 Mar 2021 19:13:46
User entered 'No (N)'	System	28 Mar 2021 19:13:46

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2021-03-28T12:13:43-07:00', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'ee8ae2e3-a382-4e5c-9b5a-c93e66d8cab7' User entered '28 Mar 2021 12:13:43'	System	28 Mar 2021 19:13:46
	System	28 Mar 2021 19:13:46

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[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 (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2021-04-04T08:44:55-07:00', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '3bb5e41e-bb8e-45dc-b728-be640c724201'	System	04 Apr 2021 15:45:16
User entered 'No (N)'	System	04 Apr 2021 15:45:16



**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

Have you been exposed to someone with 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 (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2021-04-04T08:45:07-07:00', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '3bb5e41e-bb8e-45dc-b728-be640c724201'	System	04 Apr 2021 15:45:16
User entered 'No (N)'	System	04 Apr 2021 15:45:16

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2021-04-04T08:45:13-07:00', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '3bb5e41e-bb8e-45dc-b728-be640c724201'	System	04 Apr 2021 15:45:16
User entered '04 Apr 2021 08:45:13'	System	04 Apr 2021 15:45:16

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[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 (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2021-04-11T11:16:13-07:00', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'dd0b6e45-5969-48b1-b336-35e7ed87c620'	System	11 Apr 2021 18:16:26
User entered 'No (N)'	System	11 Apr 2021 18:16:26

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

Have you been exposed to someone with 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 (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2021-04-11T11:16:16-07:00', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'dd0b6e45-5969-48b1-b336-35e7ed87c620'	System	11 Apr 2021 18:16:26
User entered 'No (N)'	System	11 Apr 2021 18:16:26

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2021-04-11T11:16:23-07:00', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'dd0b6e45-5969-48b1-b336-35e7ed87c620'	System	11 Apr 2021 18:16:26
User entered '11 Apr 2021 11:16:23'	System	11 Apr 2021 18:16:26



**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[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 (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2021-04-18T10:16:42-07:00', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'd14f9070-4331-42d4-97e6-9f6125094168'	System	18 Apr 2021 17:17:09
User entered 'No (N)'	System	18 Apr 2021 17:17:09

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Have you been exposed to someone with 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 (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2021-04-18T10:16:44-07:00', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'd14f9070-4331-42d4-97e6-9f6125094168' User entered 'No (N)'	System	18 Apr 2021 17:17:09
	System	18 Apr 2021 17:17:09

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2021-04-18T10:17:05-07:00', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'd14f9070-4331-42d4-97e6-9f6125094168'	System	18 Apr 2021 17:17:09
User entered '18 Apr 2021 10:17:05'	System	18 Apr 2021 17:17:09

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 16:08:58



**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[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 (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2021-04-25T10:06:54-07:00', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '8da2aef1-08ba-43dc-9130-838e29120874'	System	25 Apr 2021 17:07:48
User entered 'Yes (Y)'	System	25 Apr 2021 17:07:48

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

Have you been exposed to someone with 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 (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2021-04-25T10:07:03-07:00', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '8da2aef1-08ba-43dc-9130-838e29120874' User entered 'No (N)'	System	25 Apr 2021 17:07:48
	System	25 Apr 2021 17:07:48

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2021-04-25T10:07:10-07:00', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '8da2aef1-08ba-43dc-9130-838e29120874' User entered 'No (N)'	System	25 Apr 2021 17:07:48
	System	25 Apr 2021 17:07:48

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2021-04-25T10:07:22-07:00', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '8da2aef1-08ba-43dc-9130-838e29120874'	System	25 Apr 2021 17:07:48
User entered 'Yes (Y)'	System	25 Apr 2021 17:07:48

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2021-04-25T10:07:28-07:00', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '8da2aef1-08ba-43dc-9130-838e29120874'	System	25 Apr 2021 17:07:48
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	25 Apr 2021 17:07:48

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2021-04-25T10:07:37-07:00', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '8da2aef1-08ba-43dc-9130-838e29120874' User entered '25 Apr 2021 10:07:37'	System	25 Apr 2021 17:07:48
	System	25 Apr 2021 17:07:48

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 16:08:58



**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[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 (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2021-05-02T09:33:49-07:00', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '05785b79-ed45-48e0-94d6-3abcd6631335'	System	02 May 2021 16:33:56
User entered 'No (N)'	System	02 May 2021 16:33:56

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

Have you been exposed to someone with 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 (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2021-05-02T09:33:51-07:00', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '05785b79-ed45-48e0-94d6-3abcd6631335'	System	02 May 2021 16:33:56
User entered 'No (N)'	System	02 May 2021 16:33:56

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2021-05-02T09:33:54-07:00', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: '05785b79-ed45-48e0-94d6-3abcd6631335'	System	02 May 2021 16:33:56
User entered '02 May 2021 09:33:54'	System	02 May 2021 16:33:56

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 16:08:58



**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 16:08:58



**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 16:08:58



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 16:08:58



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 16:08:58



**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 16:08:58



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 16:08:58



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 16:08:58



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 16:08:58



**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 16:08:58



**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 16:08:58



**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 16:08:58



**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 16:08:58



**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 16:08:58



**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 16:08:58



**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 16:08:58



**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 16:08:58



**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 16:08:58



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 16:08:58

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 16:08:58



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 16:08:58

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 16:08:58

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 16:08:58

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 16:08:58

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 16:08:58

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 16:08:58

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 16:08:58

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 16:08:58



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 16:08:58

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 16:08:58

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 16:08:58

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 16:08:58



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 16:08:58

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 16:08:58

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 16:08:58



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 16:08:58

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 16:08:58

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 16:08:58

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 16:08:58

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 16:08:58



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 16:08:58

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 16:08:58

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 16:08:58

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 16:08:58

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 16:08:58



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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:28:58**

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 16:08:58

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 16:08:58

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 16:08:58

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 16:08:58

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 16:08:58



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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 16:08:58

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 16:08:58

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 16:08:58

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 16:08:58

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 16:08:58

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 16:08:58

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 16:08:58

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 16:08:58



**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 16:08:58



**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 16:08:58



**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 16:08:58

**US3732023**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:28:58**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:08:58
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 16:08:58



US3732023

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:28:58

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:36:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2021-02-28T05:57:34-08:00', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'a2f0e734-e3b2-4b64-90c4-b0d7054b2ffe'	System	28 Feb 2021 13:57:40
User entered 'No (N)'	System	28 Feb 2021 13:57:40

**US3732023**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 09:28:58**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:36:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0E755875-C0B2-48E3-A3C5-A72C3DEFF009)', Time: '2021-02-28T05:57:37-08:00', User OID: 'PatientReportedOutcome (US3732023)', ODM File OID: 'a2f0e734-e3b2-4b64-90c4-b0d7054b2ffe' User entered '28 Feb 2021 13:57:37'	System	28 Feb 2021 13:57:40
	System	28 Feb 2021 13:57:40

**US3732023**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:28:58**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'Yes (Y)'	Linda Vega (b) (4)	02 Nov 2020 16:53:48

US3732023

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:58

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered '02 Nov 2020' reason for change: Data Entry Error	Lauren Arnett (b) (4)	06 Nov 2020 19:42:10
User entered '2 Nov 2020'	Linda Vega (b) (4)	02 Nov 2020 16:53:48

US3732023

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'Contact Made (CONTACT MADE)'	Linda Vega (b) (4)	02 Nov 2020 16:53:48

US3732023

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:58

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered empty.	Linda Vega (b) (4)	02 Nov 2020 16:53:48

US3732023

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:28:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'Yes (Y)'	Linda Vega (b) (4)	02 Nov 2020 16:53:52

US3732023

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:28:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:27:11
User entered 'I'	System	02 Nov 2020 16:53:52



US3732023

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:11:09
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'Yes (Y)'	Sylvia Lindholm (b) (4)	04 Dec 2020 16:43:47

US3732023

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:58

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:11:09
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered '04 Dec 2020'	Sylvia Lindholm (b) (4)	04 Dec 2020 16:43:47

US3732023

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:11:09
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Sylvia Lindholm (b) (4)	04 Dec 2020 16:43:47

US3732023

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:58

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:11:09
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered empty.	Sylvia Lindholm (b) (4)	04 Dec 2020 16:43:47

US3732023

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:28:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:11:09
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'Yes (Y)'	Sylvia Lindholm (b) (4)	04 Dec 2020 16:43:54

US3732023

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:28:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:11:09
User entered 'I'	System	04 Dec 2020 16:43:54

US3732023

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:11:09
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'Yes (Y)'	Sylvia Lindholm (b) (4)	30 Dec 2020 19:43:27

US3732023

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:58

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:11:09
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered '30 Dec 2020'	Sylvia Lindholm (b) (4)	30 Dec 2020 19:43:27



US3732023

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:11:09
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Sylvia Lindholm (b) (4)	30 Dec 2020 19:43:27

US3732023

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:58

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:11:09
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered empty.	Sylvia Lindholm (b) (4)	30 Dec 2020 19:43:27

US3732023

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:28:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:11:09
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'Yes (Y)'	Sylvia Lindholm (b) (4)	30 Dec 2020 19:43:32

US3732023

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:28:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:11:09
User entered 'I'	System	30 Dec 2020 19:43:32

US3732023

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:11:09
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'Yes (Y)'	Linda Vega (b) (4)	01 Feb 2021 17:01:52
	(b) (4)	

US3732023

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:58

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:11:09
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered '01 Feb 2021'	Linda Vega (b) (4)	01 Feb 2021 17:01:52
	(b) (4)	

US3732023

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:11:09
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Linda Vega (b) (4)	01 Feb 2021 17:01:52
	(b) (4)	

US3732023

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:58

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:11:09
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered empty.	Linda Vega (b) (4)	01 Feb 2021 17:01:52
	(b) (4)	



US3732023

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:28:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:11:09
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'Yes (Y)'	Linda Vega (b) (4)	01 Feb 2021 17:01:54
	(b) (4)	

US3732023

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:28:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:11:09
User entered 'I'	System	01 Feb 2021 17:01:54

US3732023

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:28:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	15 Mar 2021 17:38:45

US3732023

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:28:58

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
User entered '15 Mar 2021'	Gordon Bovee (b) (4)	15 Mar 2021 17:38:45

US3732023

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:28:58

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
User entered 'Clinic (Clinic)'	Gordon Bovee (b) (4)	15 Mar 2021 17:38:45

**US3732023**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:28:58**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered 'VISIT4'	System	15 Mar 2021 17:38:45

US3732023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 20:54:37
User entered 'Yes (Y)'	Makenna Orel (b) (4)	30 Mar 2021 21:35:51

US3732023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 20:54:37
User entered '15 Mar 2021'	Makenna Orel (b) (4)	30 Mar 2021 21:35:51



**US3732023**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:58**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 20:54:37
User entered '08:45'	Makenna Orel (b) (4)	30 Mar 2021 21:35:51

**US3732023**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:58**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered '15 Mar 2021 08:45'	System	30 Mar 2021 21:35:51

US3732023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 20:54:37
User entered '97.3' F	Makenna Orel (b) (4)	30 Mar 2021 21:35:51

US3732023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 20:54:37
User entered 'Oral (Oral)'	(b) (4) Makenna Orel (b) (4)	30 Mar 2021 21:35:51

US3732023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 20:54:37
User entered empty.	Makenna Orel (b) (4)	30 Mar 2021 21:35:51

US3732023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 20:54:37
User entered '71'	Makenna Orel (b) (4)	30 Mar 2021 21:35:51

**US3732023**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:58**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered 'bpm'	System	30 Mar 2021 21:35:51

US3732023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:58

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 20:54:37
User entered '16'	Makenna Orel (b) (4)	30 Mar 2021 21:35:51



US3732023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered 'breaths/min'	System	30 Mar 2021 21:35:51

US3732023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 20:54:37
User entered '105'	Makenna Orel (b) (4)	30 Mar 2021 21:35:51

US3732023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered 'mmHg'	System	30 Mar 2021 21:35:51

US3732023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	14 Apr 2021 10:52:26
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 20:54:37
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Hypotension diastolic <60 not included in protocol as toxicity grading of 3. please confirm if query is correct' (Site from System).	He (Helen) Pu (b) (4)	07 Apr 2021 18:27:02
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		30 Mar 2021 21:35:51
User entered '59'	Makenna Orel (b) (4)	30 Mar 2021 21:35:51

US3732023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:58

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered 'mmHg'	System	30 Mar 2021 21:35:51

US3732023

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:28:58

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38

**US3732023**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:28:58**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38

US3732023

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:28:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	15 Mar 2021 17:39:11



**US3732023**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:28:58**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
User entered '15 Mar 2021'	Gordon Bovee (b) (4)	15 Mar 2021 17:39:11

US3732023

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:28:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	15 Mar 2021 17:39:29

US3732023

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:28:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
User entered '15 Mar 2021'	Gordon Bovee (b) (4)	15 Mar 2021 17:39:29

US3732023

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:28:58

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
User entered '08:55'	Gordon Bovee (b) (4)	15 Mar 2021 17:39:29

US3732023

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:28:58

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered '15 Mar 2021 08:55'	System	15 Mar 2021 17:39:29

US3732023

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:28:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	15 Mar 2021 17:39:40

**US3732023**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:28:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 16:55:38
User entered 'I'	System	15 Mar 2021 17:39:40

US3732023

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:10
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 20:54:37
User entered 'Yes (Y)'	(b) (4) Sylvia Lindholm (b) (4)	02 Apr 2021 18:51:38



US3732023

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:58

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:10
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 20:54:37
User entered '02 Apr 2021'	(b) (4) Sylvia Lindholm (b) (4)	02 Apr 2021 18:51:38

US3732023

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:10
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 20:54:37
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sylvia Lindholm (b) (4)	02 Apr 2021 18:51:38

US3732023

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:58

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:10
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 20:54:37
User entered empty.	(b) (4) Sylvia Lindholm (b) (4)	02 Apr 2021 18:51:38

US3732023

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:28:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:10
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 20:54:37
User entered 'Yes (Y)'	(b) (4) Sylvia Lindholm (b) (4)	02 Apr 2021 18:51:43

**US3732023**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:28:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:57:10
User entered 'I'	System	02 Apr 2021 18:51:43

US3732023

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Linda Vega (b) (4) (b) (4)	03 May 2021 22:26:04

US3732023

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:58

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '03 May 2021'	Linda Vega (b) (4) (b) (4)	03 May 2021 22:26:04

US3732023

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:28:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Linda Vega (b) (4) (b) (4)	03 May 2021 22:26:04



**US3732023**

**Folder: Safety Call Day 269 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:28:58**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User entered empty.	Linda Vega (b) (4) (b) (4)	03 May 2021 22:26:04

US3732023

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:28:58

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Linda Vega (b) (4) (b) (4)	03 May 2021 22:26:08

**US3732023**

**Folder: Safety Call Day 269 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:28:58**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 May 2021 22:26:08

US3732023

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:28:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:50:13
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	26 Jan 2021 19:37:24
	(b) (4)	

US3732023

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:28:58

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:50:13
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered '26 Jan 2021'	Gordon Bovee (b) (4)	26 Jan 2021 19:37:24
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:28:58

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:50:13
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'Clinic (Clinic)'	Gordon Bovee (b) (4)	26 Jan 2021 19:37:24
	(b) (4)	

**US3732023**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:28:58**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:50:13
User entered 'UNBLND_DECIDE'	System	26 Jan 2021 19:37:24

US3732023

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:28:58

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:50:13
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered '26 Jan 2021'	Gordon Bovee (b) (4)	26 Jan 2021 19:37:50
	(b) (4)	



**US3732023**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:28:58**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:50:13
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
	(b) (4)	
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 03:23:30

US3732023

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:28:58

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:50:13
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	26 Jan 2021 19:37:50
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:28:58

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:50:13
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
	(b) (4)	
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 03:23:30

US3732023

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:28:58

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:50:13
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered '26 Jan 2021'	Gordon Bovee (b) (4)	26 Jan 2021 19:37:50
	(b) (4)	

US3732023

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:28:58

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:50:13
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'mRNA-1273 (mRNA-1273)'	Gordon Bovee (b) (4)	26 Jan 2021 19:37:50
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:28:58

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:50:13
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'mRNA-1273 (mRNA-1273)'	Gordon Bovee (b) (4)	26 Jan 2021 19:37:50
	(b) (4)	

US3732023

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:28:58

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:50:13
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'mRNA-1273 (mRNA-1273)'	Gordon Bovee (b) (4)	26 Jan 2021 19:37:50
	(b) (4)	

US3732023

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:28:58

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:50:13
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'No (N)'	Gordon Bovee (b) (4)	26 Jan 2021 19:37:50
	(b) (4)	



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:28:58

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:50:13
User entered empty.	System	26 Jan 2021 19:37:50

**US3732023**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:28:58**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:50:13
User entered empty.	System	26 Jan 2021 19:37:50

US3732023

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:28:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:50:13
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	26 Jan 2021 19:40:09
	(b) (4)	

US3732023

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:28:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:50:13
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered '26 Jan 2021'	Gordon Bovee (b) (4)	26 Jan 2021 19:40:09
	(b) (4)	

US3732023

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:28:58

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:50:13
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered '11:05'	Gordon Bovee (b) (4)	26 Jan 2021 19:40:09
	(b) (4)	

US3732023

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:28:58

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:50:13
User entered '26 Jan 2021 11:05'	System	26 Jan 2021 19:40:09

US3732023

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:28:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:50:13
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	26 Jan 2021 19:40:34
	(b) (4)	

US3732023

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:28:58

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:50:13
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered '26 Jan 2021'	Gordon Bovee (b) (4)	26 Jan 2021 19:40:34
	(b) (4)	



US3732023

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:28:58

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:50:13
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered '10:52'	Gordon Bovee (b) (4)	26 Jan 2021 19:40:34
	(b) (4)	

**US3732023**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:28:58**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:50:13
User entered '26 Jan 2021 10:52'	System	26 Jan 2021 19:40:34

US3732023

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:28:58

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:31:44
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	06 Nov 2020 19:42:17

US3732023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:58

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:06
DataPoint activated with code reason code Data required.	Amara Yilmaz (b) (4)	04 Jan 2021 18:56:00
DataPoint inactivated with code reason code Data not required.	Amara Yilmaz (b) (4)	04 Jan 2021 18:55:54
DataPoint activated with code reason code Data required.	Amara Yilmaz (b) (4)	04 Jan 2021 18:48:14
DataPoint inactivated with code reason code Data not required.	Amara Yilmaz (b) (4)	09 Dec 2020 17:27:43
DataPoint activated with code reason code Data required.	Amara Yilmaz (b) (4)	09 Dec 2020 17:25:05
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4)	06 Nov 2020 19:43:52

US3732023

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:58

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:06
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Right cataract - version MedDRA\23.0.	Coder Import (b) (4)	04 Jan 2021 18:57:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	04 Jan 2021 18:57:44
Data point term sent to Coder	System	04 Jan 2021 18:56:26
DataPoint activated with code reason code Data required.	Amara Yilmaz (b) (4)	04 Jan 2021 18:56:00
DataPoint inactivated with code reason code Data not required.	Amara Yilmaz (b) (4)	04 Jan 2021 18:55:54
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Right cataract - version MedDRA\23.0.	Coder Import (b) (4)	04 Jan 2021 18:49:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	04 Jan 2021 18:49:30
Data point term sent to Coder	System	04 Jan 2021 18:48:18
DataPoint activated with code reason code Data required.	Amara Yilmaz (b) (4)	04 Jan 2021 18:48:14
Data point term sent to Coder	System	09 Dec 2020 17:28:33
DataPoint inactivated with code reason code Data not required.	Amara Yilmaz (b) (4)	09 Dec 2020 17:27:43
User entered 'right eye cataract'	Amara Yilmaz (b) (4)	09 Dec 2020 17:27:37
DataPoint activated with code reason code Data required.	Amara Yilmaz (b) (4)	09 Dec 2020 17:25:05
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4)	06 Nov 2020 19:43:52

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:58

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:06
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
DataPoint activated with code reason code Data required.	(b) (4) Amara Yilmaz (b) (4)	04 Jan 2021 18:56:00
DataPoint inactivated with code reason code Data not required.	(b) (4) Amara Yilmaz (b) (4)	04 Jan 2021 18:55:54
DataPoint activated with code reason code Data required.	Amara Yilmaz (b) (4)	04 Jan 2021 18:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4) Amara Yilmaz (b) (4)	09 Dec 2020 17:27:43
User entered 'Yes (Y)'	(b) (4) Amara Yilmaz (b) (4)	09 Dec 2020 17:27:37
DataPoint activated with code reason code Data required.	Amara Yilmaz (b) (4)	09 Dec 2020 17:25:05
DataPoint inactivated with code reason code Data not required.	(b) (4) Lauren Arnett (b) (4)	06 Nov 2020 19:43:52

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:58

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:06
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
DataPoint activated with code reason code Data required.	(b) (4) Amara Yilmaz (b) (4)	04 Jan 2021 18:56:00
DataPoint inactivated with code reason code Data not required.	(b) (4) Amara Yilmaz (b) (4)	04 Jan 2021 18:55:54
DataPoint activated with code reason code Data required.	Amara Yilmaz (b) (4)	04 Jan 2021 18:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4) Amara Yilmaz (b) (4)	09 Dec 2020 17:27:43
User entered 'No (N)'	(b) (4) Amara Yilmaz (b) (4)	09 Dec 2020 17:27:37
DataPoint activated with code reason code Data required.	Amara Yilmaz (b) (4)	09 Dec 2020 17:25:05
DataPoint inactivated with code reason code Data not required.	(b) (4) Lauren Arnett (b) (4)	06 Nov 2020 19:43:52

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:58

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:06
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
DataPoint activated with code reason code Data required.	(b) (4) Amara Yilmaz (b) (4)	04 Jan 2021 18:56:00
DataPoint inactivated with code reason code Data not required.	(b) (4) Amara Yilmaz (b) (4)	04 Jan 2021 18:55:54
DataPoint activated with code reason code Data required.	Amara Yilmaz (b) (4) (b) (4)	04 Jan 2021 18:48:14
DataPoint inactivated with code reason code Data not required.	Amara Yilmaz (b) (4) (b) (4)	09 Dec 2020 17:27:43
User entered 'No (N)'	Amara Yilmaz (b) (4) (b) (4)	09 Dec 2020 17:27:37
DataPoint activated with code reason code Data required.	Amara Yilmaz (b) (4) (b) (4)	09 Dec 2020 17:25:05
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4) (b) (4)	06 Nov 2020 19:43:52



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:06
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
DataPoint activated with code reason code Data required.	(b) (4)	
	Amara Yilmaz (b) (4)	04 Jan 2021 18:56:00
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Amara Yilmaz (b) (4)	04 Jan 2021 18:55:54
DataPoint activated with code reason code Data required.	(b) (4)	
	Amara Yilmaz (b) (4)	04 Jan 2021 18:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Amara Yilmaz (b) (4)	09 Dec 2020 17:27:43
User entered '06 Oct 2020'	(b) (4)	
	Amara Yilmaz (b) (4)	09 Dec 2020 17:27:37
DataPoint activated with code reason code Data required.	(b) (4)	
	Amara Yilmaz (b) (4)	09 Dec 2020 17:25:05
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Lauren Arnett (b) (4)	06 Nov 2020 19:43:52

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:58

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:06
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
DataPoint activated with code reason code Data required.	(b) (4) Amara Yilmaz (b) (4)	04 Jan 2021 18:56:00
DataPoint inactivated with code reason code Data not required.	(b) (4) Amara Yilmaz (b) (4)	04 Jan 2021 18:55:54
DataPoint activated with code reason code Data required.	Amara Yilmaz (b) (4)	04 Jan 2021 18:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4) Amara Yilmaz (b) (4)	09 Dec 2020 17:27:43
User entered empty.	(b) (4) Amara Yilmaz (b) (4)	09 Dec 2020 17:27:37
DataPoint activated with code reason code Data required.	Amara Yilmaz (b) (4)	09 Dec 2020 17:25:05
DataPoint inactivated with code reason code Data not required.	(b) (4) Lauren Arnett (b) (4)	06 Nov 2020 19:43:52

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:58

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:06
DataPoint activated with code reason code Data required.	Amara Yilmaz (b) (4)	04 Jan 2021 18:56:00
DataPoint inactivated with code reason code Data not required.	Amara Yilmaz (b) (4)	04 Jan 2021 18:55:54
DataPoint activated with code reason code Data required.	Amara Yilmaz (b) (4)	04 Jan 2021 18:48:14
DataPoint inactivated with code reason code Data not required.	Amara Yilmaz (b) (4)	09 Dec 2020 17:27:43
User entered empty.	System	09 Dec 2020 17:27:37
DataPoint activated with code reason code Data required.	Amara Yilmaz (b) (4)	09 Dec 2020 17:25:05
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4)	06 Nov 2020 19:43:52

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:06
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
User entered 'No (N)' reason for change: New Information	Amara Yilmaz (b) (4)	04 Jan 2021 18:56:46
DataPoint activated with code reason code Data required.	Amara Yilmaz (b) (4)	04 Jan 2021 18:56:00
DataPoint inactivated with code reason code Data not required.	Amara Yilmaz (b) (4)	04 Jan 2021 18:55:54
DataPoint activated with code reason code Data required.	Amara Yilmaz (b) (4)	04 Jan 2021 18:48:14
DataPoint inactivated with code reason code Data not required.	Amara Yilmaz (b) (4)	09 Dec 2020 17:27:43
User entered 'Yes (Y)'	Amara Yilmaz (b) (4)	09 Dec 2020 17:27:37
DataPoint activated with code reason code Data required.	Amara Yilmaz (b) (4)	09 Dec 2020 17:25:05
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4)	06 Nov 2020 19:43:52

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:58

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:06
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
User entered '10 Dec 2020' reason for change: Data Entry Error	(b) (4)	
	Amara Yilmaz (b) (4)	04 Jan 2021 18:56:46
DataPoint activated with code reason code Data required.	(b) (4)	
	Amara Yilmaz (b) (4)	04 Jan 2021 18:56:00
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Amara Yilmaz (b) (4)	04 Jan 2021 18:55:54
DataPoint activated with code reason code Data required.	(b) (4)	
	Amara Yilmaz (b) (4)	04 Jan 2021 18:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Amara Yilmaz (b) (4)	09 Dec 2020 17:27:43
User entered empty.	(b) (4)	
	Amara Yilmaz (b) (4)	09 Dec 2020 17:27:37
DataPoint activated with code reason code Data required.	(b) (4)	
	Amara Yilmaz (b) (4)	09 Dec 2020 17:25:05
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Lauren Arnett (b) (4)	06 Nov 2020 19:43:52

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:58

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:06
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
DataPoint activated with code reason code Data required.	(b) (4) Amara Yilmaz (b) (4)	04 Jan 2021 18:56:00
DataPoint inactivated with code reason code Data not required.	(b) (4) Amara Yilmaz (b) (4)	04 Jan 2021 18:55:54
DataPoint activated with code reason code Data required.	Amara Yilmaz (b) (4)	04 Jan 2021 18:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4) Amara Yilmaz (b) (4)	09 Dec 2020 17:27:43
User entered empty.	(b) (4) Amara Yilmaz (b) (4)	09 Dec 2020 17:27:37
DataPoint activated with code reason code Data required.	Amara Yilmaz (b) (4)	09 Dec 2020 17:25:05
DataPoint inactivated with code reason code Data not required.	(b) (4) Lauren Arnett (b) (4)	06 Nov 2020 19:43:52

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:58

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:06
DataPoint activated with code reason code Data required.	Amara Yilmaz (b) (4)	04 Jan 2021 18:56:00
DataPoint inactivated with code reason code Data not required.	Amara Yilmaz (b) (4)	04 Jan 2021 18:55:54
DataPoint activated with code reason code Data required.	Amara Yilmaz (b) (4)	04 Jan 2021 18:48:14
DataPoint inactivated with code reason code Data not required.	Amara Yilmaz (b) (4)	09 Dec 2020 17:27:43
User entered empty.	System	09 Dec 2020 17:27:37
DataPoint activated with code reason code Data required.	Amara Yilmaz (b) (4)	09 Dec 2020 17:25:05
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4)	06 Nov 2020 19:43:52

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:58

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:06
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
User entered 'Grade 2/Moderate (Grade 2/Moderate) reason for change: Data Entry Error	(b) (4) Amara Yilmaz (b) (4)	06 Jan 2021 18:43:22
DataPoint activated with code reason code Data required.	(b) (4) Amara Yilmaz (b) (4)	04 Jan 2021 18:56:00
DataPoint inactivated with code reason code Data not required.	(b) (4) Amara Yilmaz (b) (4)	04 Jan 2021 18:55:54
DataPoint activated with code reason code Data required.	(b) (4) Amara Yilmaz (b) (4)	04 Jan 2021 18:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4) Amara Yilmaz (b) (4)	09 Dec 2020 17:27:43
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Amara Yilmaz (b) (4)	09 Dec 2020 17:27:37
DataPoint activated with code reason code Data required.	(b) (4) Amara Yilmaz (b) (4)	09 Dec 2020 17:25:05
DataPoint inactivated with code reason code Data not required.	(b) (4) Lauren Arnett (b) (4)	06 Nov 2020 19:43:52



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Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:58

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:06
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
DataPoint activated with code reason code Data required.	(b) (4) Amara Yilmaz (b) (4)	04 Jan 2021 18:56:00
DataPoint inactivated with code reason code Data not required.	(b) (4) Amara Yilmaz (b) (4)	04 Jan 2021 18:55:54
DataPoint activated with code reason code Data required.	Amara Yilmaz (b) (4)	04 Jan 2021 18:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4) Amara Yilmaz (b) (4)	09 Dec 2020 17:27:43
User entered 'No (N)'	(b) (4) Amara Yilmaz (b) (4)	09 Dec 2020 17:27:37
DataPoint activated with code reason code Data required.	Amara Yilmaz (b) (4)	09 Dec 2020 17:25:05
DataPoint inactivated with code reason code Data not required.	(b) (4) Lauren Arnett (b) (4)	06 Nov 2020 19:43:52

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Folder: Adverse Events

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Generated On: 10 Jun 2021 09:28:58

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:06
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
DataPoint activated with code reason code Data required.	(b) (4)	
	Amara Yilmaz (b) (4)	04 Jan 2021 18:56:00
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Amara Yilmaz (b) (4)	04 Jan 2021 18:55:54
DataPoint activated with code reason code Data required.	(b) (4)	
	Amara Yilmaz (b) (4)	04 Jan 2021 18:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Amara Yilmaz (b) (4)	09 Dec 2020 17:27:43
User entered '0'	(b) (4)	
	Amara Yilmaz (b) (4)	09 Dec 2020 17:27:37
DataPoint activated with code reason code Data required.	(b) (4)	
	Amara Yilmaz (b) (4)	09 Dec 2020 17:25:05
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Lauren Arnett (b) (4)	06 Nov 2020 19:43:52

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:58

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:06
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
DataPoint activated with code reason code Data required.	(b) (4) Amara Yilmaz (b) (4)	04 Jan 2021 18:56:00
DataPoint inactivated with code reason code Data not required.	(b) (4) Amara Yilmaz (b) (4)	04 Jan 2021 18:55:54
DataPoint activated with code reason code Data required.	Amara Yilmaz (b) (4)	04 Jan 2021 18:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4) Amara Yilmaz (b) (4)	09 Dec 2020 17:27:43
User entered '0'	(b) (4) Amara Yilmaz (b) (4)	09 Dec 2020 17:27:37
DataPoint activated with code reason code Data required.	(b) (4) Amara Yilmaz (b) (4)	09 Dec 2020 17:25:05
DataPoint inactivated with code reason code Data not required.	(b) (4) Lauren Arnett (b) (4)	06 Nov 2020 19:43:52

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:06
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
DataPoint activated with code reason code Data required.	(b) (4) Amara Yilmaz (b) (4)	04 Jan 2021 18:56:00
DataPoint inactivated with code reason code Data not required.	(b) (4) Amara Yilmaz (b) (4)	04 Jan 2021 18:55:54
DataPoint activated with code reason code Data required.	Amara Yilmaz (b) (4)	04 Jan 2021 18:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4) Amara Yilmaz (b) (4)	09 Dec 2020 17:27:43
User entered '0'	(b) (4) Amara Yilmaz (b) (4)	09 Dec 2020 17:27:37
DataPoint activated with code reason code Data required.	(b) (4) Amara Yilmaz (b) (4)	09 Dec 2020 17:25:05
DataPoint inactivated with code reason code Data not required.	(b) (4) Lauren Arnett (b) (4)	06 Nov 2020 19:43:52

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:58

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:06
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
DataPoint activated with code reason code Data required.	(b) (4) Amara Yilmaz (b) (4)	04 Jan 2021 18:56:00
DataPoint inactivated with code reason code Data not required.	(b) (4) Amara Yilmaz (b) (4)	04 Jan 2021 18:55:54
DataPoint activated with code reason code Data required.	(b) (4) Amara Yilmaz (b) (4)	04 Jan 2021 18:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4) Amara Yilmaz (b) (4)	09 Dec 2020 17:27:43
User entered empty.	(b) (4) Amara Yilmaz (b) (4)	09 Dec 2020 17:27:37
DataPoint activated with code reason code Data required.	(b) (4) Amara Yilmaz (b) (4)	09 Dec 2020 17:25:05
DataPoint inactivated with code reason code Data not required.	(b) (4) Lauren Arnett (b) (4)	06 Nov 2020 19:43:52

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:58

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:06
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
DataPoint activated with code reason code Data required.	(b) (4) Amara Yilmaz (b) (4)	04 Jan 2021 18:56:00
DataPoint inactivated with code reason code Data not required.	(b) (4) Amara Yilmaz (b) (4)	04 Jan 2021 18:55:54
DataPoint activated with code reason code Data required.	Amara Yilmaz (b) (4)	04 Jan 2021 18:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4) Amara Yilmaz (b) (4)	09 Dec 2020 17:27:43
User entered empty.	(b) (4) Amara Yilmaz (b) (4)	09 Dec 2020 17:27:37
DataPoint activated with code reason code Data required.	(b) (4) Amara Yilmaz (b) (4)	09 Dec 2020 17:25:05
DataPoint inactivated with code reason code Data not required.	(b) (4) Lauren Arnett (b) (4)	06 Nov 2020 19:43:52

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:58

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:06
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
DataPoint activated with code reason code Data required.	(b) (4) Amara Yilmaz (b) (4)	04 Jan 2021 18:56:00
DataPoint inactivated with code reason code Data not required.	(b) (4) Amara Yilmaz (b) (4)	04 Jan 2021 18:55:54
DataPoint activated with code reason code Data required.	Amara Yilmaz (b) (4)	04 Jan 2021 18:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4) Amara Yilmaz (b) (4)	09 Dec 2020 17:27:43
User entered empty.	(b) (4) Amara Yilmaz (b) (4)	09 Dec 2020 17:27:37
DataPoint activated with code reason code Data required.	Amara Yilmaz (b) (4)	09 Dec 2020 17:25:05
DataPoint inactivated with code reason code Data not required.	(b) (4) Lauren Arnett (b) (4)	06 Nov 2020 19:43:52

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:58

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:06
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
DataPoint activated with code reason code Data required.	(b) (4) Amara Yilmaz (b) (4)	04 Jan 2021 18:56:00
DataPoint inactivated with code reason code Data not required.	(b) (4) Amara Yilmaz (b) (4)	04 Jan 2021 18:55:54
DataPoint activated with code reason code Data required.	Amara Yilmaz (b) (4)	04 Jan 2021 18:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4) Amara Yilmaz (b) (4)	09 Dec 2020 17:27:43
User entered empty.	(b) (4) Amara Yilmaz (b) (4)	09 Dec 2020 17:27:37
DataPoint activated with code reason code Data required.	Amara Yilmaz (b) (4)	09 Dec 2020 17:25:05
DataPoint inactivated with code reason code Data not required.	(b) (4) Lauren Arnett (b) (4)	06 Nov 2020 19:43:52



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Folder: Adverse Events

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Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:06
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
DataPoint activated with code reason code Data required.	(b) (4) Amara Yilmaz (b) (4)	04 Jan 2021 18:56:00
DataPoint inactivated with code reason code Data not required.	(b) (4) Amara Yilmaz (b) (4)	04 Jan 2021 18:55:54
DataPoint activated with code reason code Data required.	Amara Yilmaz (b) (4) (b) (4)	04 Jan 2021 18:48:14
DataPoint inactivated with code reason code Data not required.	Amara Yilmaz (b) (4) (b) (4)	09 Dec 2020 17:27:43
User entered '0'	Amara Yilmaz (b) (4) (b) (4)	09 Dec 2020 17:27:37
DataPoint activated with code reason code Data required.	Amara Yilmaz (b) (4) (b) (4)	09 Dec 2020 17:25:05
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4) (b) (4)	06 Nov 2020 19:43:52

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Folder: Adverse Events

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Generated On: 10 Jun 2021 09:28:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:06
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
DataPoint activated with code reason code Data required.	(b) (4) Amara Yilmaz (b) (4)	04 Jan 2021 18:56:00
DataPoint inactivated with code reason code Data not required.	(b) (4) Amara Yilmaz (b) (4)	04 Jan 2021 18:55:54
DataPoint activated with code reason code Data required.	Amara Yilmaz (b) (4)	04 Jan 2021 18:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4) Amara Yilmaz (b) (4)	09 Dec 2020 17:27:43
User entered '0'	(b) (4) Amara Yilmaz (b) (4)	09 Dec 2020 17:27:37
DataPoint activated with code reason code Data required.	Amara Yilmaz (b) (4)	09 Dec 2020 17:25:05
DataPoint inactivated with code reason code Data not required.	(b) (4) Lauren Arnett (b) (4)	06 Nov 2020 19:43:52

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:06
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
DataPoint activated with code reason code Data required.	(b) (4) Amara Yilmaz (b) (4)	04 Jan 2021 18:56:00
DataPoint inactivated with code reason code Data not required.	(b) (4) Amara Yilmaz (b) (4)	04 Jan 2021 18:55:54
DataPoint activated with code reason code Data required.	Amara Yilmaz (b) (4)	04 Jan 2021 18:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4) Amara Yilmaz (b) (4)	09 Dec 2020 17:27:43
User entered '0'	(b) (4) Amara Yilmaz (b) (4)	09 Dec 2020 17:27:37
DataPoint activated with code reason code Data required.	Amara Yilmaz (b) (4)	09 Dec 2020 17:25:05
DataPoint inactivated with code reason code Data not required.	(b) (4) Lauren Arnett (b) (4)	06 Nov 2020 19:43:52

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:06
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
DataPoint activated with code reason code Data required.	(b) (4) Amara Yilmaz (b) (4)	04 Jan 2021 18:56:00
DataPoint inactivated with code reason code Data not required.	(b) (4) Amara Yilmaz (b) (4)	04 Jan 2021 18:55:54
DataPoint activated with code reason code Data required.	Amara Yilmaz (b) (4) (b) (4)	04 Jan 2021 18:48:14
DataPoint inactivated with code reason code Data not required.	Amara Yilmaz (b) (4) (b) (4)	09 Dec 2020 17:27:43
User entered 'Not Related (NOT RELATED)'	Amara Yilmaz (b) (4) (b) (4)	09 Dec 2020 17:27:37
DataPoint activated with code reason code Data required.	Amara Yilmaz (b) (4) (b) (4)	09 Dec 2020 17:25:05
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4) (b) (4)	06 Nov 2020 19:43:52

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Folder: Adverse Events

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:06
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
DataPoint activated with code reason code Data required.	(b) (4) Amara Yilmaz (b) (4)	04 Jan 2021 18:56:00
DataPoint inactivated with code reason code Data not required.	(b) (4) Amara Yilmaz (b) (4)	04 Jan 2021 18:55:54
DataPoint activated with code reason code Data required.	Amara Yilmaz (b) (4)	04 Jan 2021 18:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4) Amara Yilmaz (b) (4)	09 Dec 2020 17:27:43
User entered 'Not Related (NOT RELATED)'	(b) (4) Amara Yilmaz (b) (4)	09 Dec 2020 17:27:37
DataPoint activated with code reason code Data required.	Amara Yilmaz (b) (4)	09 Dec 2020 17:25:05
DataPoint inactivated with code reason code Data not required.	(b) (4) Lauren Arnett (b) (4)	06 Nov 2020 19:43:52

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Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:06
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
DataPoint activated with code reason code Data required.	(b) (4) Amara Yilmaz (b) (4)	04 Jan 2021 18:56:00
DataPoint inactivated with code reason code Data not required.	(b) (4) Amara Yilmaz (b) (4)	04 Jan 2021 18:55:54
DataPoint activated with code reason code Data required.	Amara Yilmaz (b) (4)	04 Jan 2021 18:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4) Amara Yilmaz (b) (4)	09 Dec 2020 17:27:43
User entered 'None (NONE)'	(b) (4) Amara Yilmaz (b) (4)	09 Dec 2020 17:27:37
DataPoint activated with code reason code Data required.	Amara Yilmaz (b) (4)	09 Dec 2020 17:25:05
DataPoint inactivated with code reason code Data not required.	(b) (4) Lauren Arnett (b) (4)	06 Nov 2020 19:43:52

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None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:06
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
User entered '0' reason for change: Data Entry Error	(b) (4)	
	Amara Yilmaz (b) (4)	06 Jan 2021 18:43:22
	(b) (4)	
DataPoint activated with code reason code Data required.	Amara Yilmaz (b) (4)	04 Jan 2021 18:56:00
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Amara Yilmaz (b) (4)	04 Jan 2021 18:55:54
	(b) (4)	
DataPoint activated with code reason code Data required.	Amara Yilmaz (b) (4)	04 Jan 2021 18:48:14
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Amara Yilmaz (b) (4)	09 Dec 2020 17:27:43
	(b) (4)	
User entered '1'	Amara Yilmaz (b) (4)	09 Dec 2020 17:27:37
	(b) (4)	
DataPoint activated with code reason code Data required.	Amara Yilmaz (b) (4)	09 Dec 2020 17:25:05
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4)	06 Nov 2020 19:43:52
	(b) (4)	

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:06
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Amara Yilmaz (b) (4)	06 Jan 2021 18:43:22
DataPoint activated with code reason code Data required.	(b) (4)	
	Amara Yilmaz (b) (4)	04 Jan 2021 18:56:00
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Amara Yilmaz (b) (4)	04 Jan 2021 18:55:54
DataPoint activated with code reason code Data required.	(b) (4)	
	Amara Yilmaz (b) (4)	04 Jan 2021 18:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Amara Yilmaz (b) (4)	09 Dec 2020 17:27:43
User entered '0'	(b) (4)	
	Amara Yilmaz (b) (4)	09 Dec 2020 17:27:37
DataPoint activated with code reason code Data required.	(b) (4)	
	Amara Yilmaz (b) (4)	09 Dec 2020 17:25:05
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Lauren Arnett (b) (4)	06 Nov 2020 19:43:52



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:28:58

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:06
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Amara Yilmaz (b) (4)	06 Jan 2021 18:43:22
DataPoint activated with code reason code Data required.	(b) (4)	
	Amara Yilmaz (b) (4)	04 Jan 2021 18:56:00
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Amara Yilmaz (b) (4)	04 Jan 2021 18:55:54
DataPoint activated with code reason code Data required.	(b) (4)	
	Amara Yilmaz (b) (4)	04 Jan 2021 18:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Amara Yilmaz (b) (4)	09 Dec 2020 17:27:43
User entered '0'	(b) (4)	
	Amara Yilmaz (b) (4)	09 Dec 2020 17:27:37
DataPoint activated with code reason code Data required.	(b) (4)	
	Amara Yilmaz (b) (4)	09 Dec 2020 17:25:05
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Lauren Arnett (b) (4)	06 Nov 2020 19:43:52

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:06
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Amara Yilmaz (b) (4)	04 Jan 2021 18:56:46
DataPoint activated with code reason code Data required.	Amara Yilmaz (b) (4)	04 Jan 2021 18:56:00
DataPoint inactivated with code reason code Data not required.	Amara Yilmaz (b) (4)	04 Jan 2021 18:55:54
DataPoint activated with code reason code Data required.	Amara Yilmaz (b) (4)	04 Jan 2021 18:48:14
DataPoint inactivated with code reason code Data not required.	Amara Yilmaz (b) (4)	09 Dec 2020 17:27:43
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Amara Yilmaz (b) (4)	09 Dec 2020 17:27:37
DataPoint activated with code reason code Data required.	Amara Yilmaz (b) (4)	09 Dec 2020 17:25:05
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4)	06 Nov 2020 19:43:52

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Form: Adverse Events (1)

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:06
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
DataPoint activated with code reason code Data required.	(b) (4) Amara Yilmaz (b) (4)	04 Jan 2021 18:56:00
DataPoint inactivated with code reason code Data not required.	(b) (4) Amara Yilmaz (b) (4)	04 Jan 2021 18:55:54
DataPoint activated with code reason code Data required.	(b) (4) Amara Yilmaz (b) (4)	04 Jan 2021 18:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4) Amara Yilmaz (b) (4)	09 Dec 2020 17:27:43
User entered empty.	(b) (4) Amara Yilmaz (b) (4)	09 Dec 2020 17:27:37
DataPoint activated with code reason code Data required.	(b) (4) Amara Yilmaz (b) (4)	09 Dec 2020 17:25:05
DataPoint inactivated with code reason code Data not required.	(b) (4) Lauren Arnett (b) (4)	06 Nov 2020 19:43:52

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:06
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
DataPoint activated with code reason code Data required.	(b) (4) Amara Yilmaz (b) (4)	04 Jan 2021 18:56:00
DataPoint inactivated with code reason code Data not required.	(b) (4) Amara Yilmaz (b) (4)	04 Jan 2021 18:55:54
DataPoint activated with code reason code Data required.	Amara Yilmaz (b) (4)	04 Jan 2021 18:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4) Amara Yilmaz (b) (4)	09 Dec 2020 17:27:43
User entered empty.	(b) (4) Amara Yilmaz (b) (4)	09 Dec 2020 17:27:37
DataPoint activated with code reason code Data required.	Amara Yilmaz (b) (4)	09 Dec 2020 17:25:05
DataPoint inactivated with code reason code Data not required.	(b) (4) Lauren Arnett (b) (4)	06 Nov 2020 19:43:52

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Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:06
DataPoint activated with code reason code Data required.	Amara Yilmaz (b) (4)	04 Jan 2021 18:56:00
DataPoint inactivated with code reason code Data not required.	Amara Yilmaz (b) (4)	04 Jan 2021 18:55:54
DataPoint activated with code reason code Data required.	Amara Yilmaz (b) (4)	04 Jan 2021 18:48:14
DataPoint inactivated with code reason code Data not required.	Amara Yilmaz (b) (4)	09 Dec 2020 17:27:43
User entered '0'	System	09 Dec 2020 17:27:37
DataPoint activated with code reason code Data required.	Amara Yilmaz (b) (4)	09 Dec 2020 17:25:05
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4)	06 Nov 2020 19:43:52

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Form: Adverse Events (1)

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Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:06
DataPoint activated with code reason code Data required.	Amara Yilmaz (b) (4)	04 Jan 2021 18:56:00
DataPoint inactivated with code reason code Data not required.	Amara Yilmaz (b) (4)	04 Jan 2021 18:55:54
DataPoint activated with code reason code Data required.	Amara Yilmaz (b) (4)	04 Jan 2021 18:48:14
DataPoint inactivated with code reason code Data not required.	Amara Yilmaz (b) (4)	09 Dec 2020 17:27:43
User entered 'I'	System	09 Dec 2020 17:27:37
DataPoint activated with code reason code Data required.	Amara Yilmaz (b) (4)	09 Dec 2020 17:25:05
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4)	06 Nov 2020 19:43:52

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Form: Adverse Events (1)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:02:06
DataPoint activated with code reason code Data required.	Amara Yilmaz (b) (4)	04 Jan 2021 18:56:00
DataPoint inactivated with code reason code Data not required.	(b) (4)	04 Jan 2021 18:55:54
DataPoint activated with code reason code Data required.	Amara Yilmaz (b) (4)	04 Jan 2021 18:48:14
DataPoint inactivated with code reason code Data not required.	(b) (4)	09 Dec 2020 17:27:43
DataPoint activated with code reason code Data required.	Amara Yilmaz (b) (4)	09 Dec 2020 17:25:05
DataPoint inactivated with code reason code Data not required.	Lauren Arnett (b) (4)	06 Nov 2020 19:43:52

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:56



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Folder: Adverse Events

Form: Adverse Events (2)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:56
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Left cataract - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	04 Feb 2021 19:05:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Feb 2021 19:05:51
Data point term sent to Coder	System	04 Feb 2021 19:04:46
User entered 'Left eye cataract'	Gordon Bovee (b) (4) (b) (4)	04 Feb 2021 19:04:42

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:28:58**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:56
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	04 Feb 2021 19:04:42

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:28:58**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:56
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
User entered 'No (N)'	Gordon Bovee (b) (4)	04 Feb 2021 19:04:42

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:56
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
User entered 'No (N)'	Gordon Bovee (b) (4)	04 Feb 2021 19:04:42

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Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:56
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
User entered '06 Oct 2020'	Gordon Bovee (b) (4)	04 Feb 2021 19:04:42

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:28:58**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:56
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
User entered empty.	Gordon Bovee (b) (4)	04 Feb 2021 19:04:42

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Form: Adverse Events (2)

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:56
User entered empty.	System	04 Feb 2021 19:04:42

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:28:58**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:56
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
User entered 'No (N)' reason for change: New Information	(b) (4) Gordon Bovee (b) (4)	16 Mar 2021 16:16:09
User entered 'Yes (Y)'	(b) (4) Gordon Bovee (b) (4)	04 Feb 2021 19:04:42



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Generated On: 10 Jun 2021 09:28:58

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:56
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	(b) (4)	16 Mar 2021 16:16:09
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	16 Mar 2021 16:16:09
User entered '25 Feb 2021' reason for change: New Information	Gordon Bovee (b) (4)	16 Mar 2021 16:16:09
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	16 Mar 2021 16:15:40
User entered empty.	Gordon Bovee (b) (4)	04 Feb 2021 19:04:42

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:28:58**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:56
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
User entered empty.	Gordon Bovee (b) (4)	04 Feb 2021 19:04:42

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:58

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:56
User entered empty.	System	04 Feb 2021 19:04:42

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:58

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:56
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Mar 2021 16:15:40
User entered 'Grade 2/Moderate (Grade 2/Moderate) reason for change: New Information	System	16 Mar 2021 16:15:40
User opened query 'Data is required. Please complete.' (Site from System).	Gordon Bovee (b) (4)	16 Mar 2021 16:15:40
User entered empty.	(b) (4)	
	System	04 Feb 2021 19:04:42
	Gordon Bovee (b) (4)	04 Feb 2021 19:04:42
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:58

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:56
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Mar 2021 16:15:40
User entered 'No (N)' reason for change: New Information	Gordon Bovee (b) (4)	16 Mar 2021 16:15:40
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Feb 2021 19:04:42
User entered empty.	Gordon Bovee (b) (4)	04 Feb 2021 19:04:42

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:28:58**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:56
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
User entered '0'	Gordon Bovee (b) (4)	04 Feb 2021 19:04:42

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Folder: Adverse Events

Form: Adverse Events (2)

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:56
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
User entered '0'	Gordon Bovee (b) (4)	04 Feb 2021 19:04:42

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:28:58**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:56
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
User entered '0'	Gordon Bovee (b) (4)	04 Feb 2021 19:04:42



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Folder: Adverse Events

Form: Adverse Events (2)

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:56
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
User entered empty.	Gordon Bovee (b) (4)	04 Feb 2021 19:04:42

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:58

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:56
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
User entered empty.	Gordon Bovee (b) (4)	04 Feb 2021 19:04:42

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:56
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
User entered empty.	Gordon Bovee (b) (4)	04 Feb 2021 19:04:42

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Folder: Adverse Events

Form: Adverse Events (2)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:56
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
User entered empty.	Gordon Bovee (b) (4)	04 Feb 2021 19:04:42

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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)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:56
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
User entered '0'	Gordon Bovee (b) (4)	04 Feb 2021 19:04:42

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Folder: Adverse Events

Form: Adverse Events (2)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:56
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
User entered '0'	Gordon Bovee (b) (4)	04 Feb 2021 19:04:42

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Folder: Adverse Events

Form: Adverse Events (2)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:56
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
User entered '0'	Gordon Bovee (b) (4)	04 Feb 2021 19:04:42

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:58

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:56
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
User entered 'Not Applicable (NOT APPLICABLE)'	Gordon Bovee (b) (4)	04 Feb 2021 19:04:42



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:58

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:56
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
User entered 'Not Applicable (NOT APPLICABLE)'	Gordon Bovee (b) (4)	04 Feb 2021 19:04:42

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Folder: Adverse Events

Form: Adverse Events (2)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:56
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
User entered 'Not Applicable (NOT APPLICABLE)'	Gordon Bovee (b) (4)	04 Feb 2021 19:04:42

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:28:58

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:56
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 20:54:37
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication and Concomitant procedure recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 17:52:20
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication and Concomitant procedure recorded that matches this AE during this timeframe. Please review and update this field. ' answered with 'updated' (Site from DM).	He (Helen) Pu (b) (4)	07 Apr 2021 18:32:13
Signature has been broken.	He (Helen) Pu (b) (4)	07 Apr 2021 18:32:08
User entered '0' reason for change: Data Entry Error	He (Helen) Pu (b) (4)	07 Apr 2021 18:32:08
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication and Concomitant procedure recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 13:52:34
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
User entered '1'	Gordon Bovee (b) (4)	04 Feb 2021 19:04:42

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:56
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 20:54:37
Signature has been broken.	He (Helen) Pu (b) (4)	07 Apr 2021 18:32:08
User entered '1' reason for change: Data Entry Error	He (Helen) Pu (b) (4)	07 Apr 2021 18:32:08
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
User entered '0'	Gordon Bovee (b) (4)	04 Feb 2021 19:04:42

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Folder: Adverse Events

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:56
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 20:54:37
Signature has been broken.	He (Helen) Pu (b) (4)	07 Apr 2021 18:32:08
User entered '1' reason for change: Data Entry Error	He (Helen) Pu (b) (4)	07 Apr 2021 18:32:08
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
User entered '0'	Gordon Bovee (b) (4)	04 Feb 2021 19:04:42

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:56
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	16 Mar 2021 16:15:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Mar 2021 16:15:40
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Gordon Bovee (b) (4)	16 Mar 2021 16:15:40
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Feb 2021 19:04:42
User entered empty.	Gordon Bovee (b) (4)	04 Feb 2021 19:04:42

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:56
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
User entered empty.	Gordon Bovee (b) (4)	04 Feb 2021 19:04:42

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:56
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
User entered empty.	Gordon Bovee (b) (4)	04 Feb 2021 19:04:42



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**Folder: Adverse Events**

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:56
User entered '0'	System	16 Mar 2021 16:15:40

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**Folder: Adverse Events**

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:56
User entered 'I'	System	04 Feb 2021 19:04:42

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**Folder: Adverse Events**

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:56

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Folder: Adverse Events

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[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Mononeuropathies, PT: Nerve compression, LLT: Pinched nerve - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	27 Apr 2021 01:27:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Apr 2021 01:27:50
Data point term sent to Coder	System	26 Apr 2021 23:18:14
User entered 'left hip pinched nerve'	Linda Vega (b) (4) (b) (4)	26 Apr 2021 23:17:25

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered 'Yes (Y)'	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 23:17:25

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered 'No (N)'	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 23:17:25

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**Folder: Adverse Events**

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered 'No (N)'	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 23:17:25

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
	(b) (4)	
User entered '16 Apr 2021'	Linda Vega (b) (4)	26 Apr 2021 23:17:25
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:58**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered empty.	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 23:17:25

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Apr 2021 23:17:25

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:58**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered 'Yes (Y)'	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 23:17:25

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If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
	(b) (4)	
User entered empty.	Linda Vega (b) (4)	26 Apr 2021 23:17:25
	(b) (4)	

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[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered empty.	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 23:17:25

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Apr 2021 23:17:25

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**Folder: Adverse Events**

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 23:17:25

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
	(b) (4)	
User entered 'No (N)'	Linda Vega (b) (4)	26 Apr 2021 23:17:25
	(b) (4)	



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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered '0'	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 23:17:25

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
	(b) (4)	
User entered '0'	Linda Vega (b) (4)	26 Apr 2021 23:17:25
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:58**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered '0'	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 23:17:25

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Folder: Adverse Events

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered empty.	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 23:17:25

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:28:58

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered empty.	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 23:17:25

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:58**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
	(b) (4)	
User entered empty.	Linda Vega (b) (4)	26 Apr 2021 23:17:25
	(b) (4)	

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered empty.	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 23:17:25

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Folder: Adverse Events

Form: Adverse Events (3)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered '0'	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 23:17:25



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Form: Adverse Events (3)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered '0'	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 23:17:25

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**Folder: Adverse Events**

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
	(b) (4)	
User entered '0'	Linda Vega (b) (4)	26 Apr 2021 23:17:25
	(b) (4)	

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 23:17:25

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:28:58

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 23:17:25

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 23:17:25

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Folder: Adverse Events

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None

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	26 Apr 2021 23:17:40
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	26 Apr 2021 23:17:25
User entered '0'	Linda Vega (b) (4) (b) (4)	26 Apr 2021 23:17:25

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Linda Vega (b) (4)	26 Apr 2021 23:17:40
	(b) (4)	
User entered '0'	Linda Vega (b) (4)	26 Apr 2021 23:17:25
	(b) (4)	

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
	(b) (4)	
User entered '0'	Linda Vega (b) (4)	26 Apr 2021 23:17:25
	(b) (4)	



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Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:28:58

[Outcome](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	29 Apr 2021 21:02:04
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
Query 'Data is required. Please complete.' answered with 'open ae - ongoing' (Site from System).	(b) (4)	28 Apr 2021 17:42:46
User opened query 'Data is required. Please complete.' (Site from System).	He (Helen) Pu (b) (4)	26 Apr 2021 23:17:25
User entered empty.	System	26 Apr 2021 23:17:25
	Linda Vega (b) (4)	26 Apr 2021 23:17:25
	(b) (4)	

**US3732023**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:58**

[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 22:19:26
User entered empty.	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 23:17:25

**US3732023**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:58**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered empty.	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 23:17:25

**US3732023**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:58**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	26 Apr 2021 23:17:25

**US3732023**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:28:58**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Apr 2021 23:17:25

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:58

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered 'USA-US102-2021-mRNA-1273-P301000009'	(b) (4) System	27 Apr 2021 14:02:19
User entered 'New'	(b) (4), (b) (6)	27 Apr 2021 14:02:19

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:58

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Hip fracture, LLT: Broken hip - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	26 Apr 2021 23:21:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Apr 2021 23:21:55
Data point term sent to Coder	System	26 Apr 2021 23:21:15
User entered 'broken hip'	Linda Vega (b) (4) (b) (4)	26 Apr 2021 23:20:48

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:58

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered 'Yes (Y)'	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 23:20:48



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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:28:58**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered 'No (N)'	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 23:20:48

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:58

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered 'No (N)'	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 23:20:48

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered '22 Apr 2021'	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 23:20:48

**US3732023**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:28:58**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered empty.	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 23:20:48

**US3732023**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:28:58**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Apr 2021 23:20:48

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered 'Yes (Y)'	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 23:20:48

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:58

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered empty.	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 23:20:48

**US3732023**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:28:58**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered empty.	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 23:20:48



**US3732023**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:28:58**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Apr 2021 23:20:48

**US3732023**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:28:58**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 23:20:48

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:58

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
	(b) (4)	
User entered 'Yes (Y)'	Linda Vega (b) (4)	26 Apr 2021 23:20:48
	(b) (4)	

**US3732023**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:28:58**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered '0'	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 23:20:48

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:58

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered '0'	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 23:20:48

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:58

[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)	29 Apr 2021 21:02:22
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
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 'pending medical records - as of 26Apr2021 still hospitalized' (Site from System).	He (Helen) Pu (b) (4)	28 Apr 2021 17:43:25
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	26 Apr 2021 23:20:48
User entered 'I'	Linda Vega (b) (4)	26 Apr 2021 23:20:48

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:58

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered '23 Apr 2021'	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 23:20:48

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:58

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered empty.	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 23:20:48



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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:28:58**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered empty.	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 23:20:48

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:58

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered empty.	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 23:20:48

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered '0'	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 23:20:48

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered '0'	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 23:20:48

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:58

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered '0'	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 23:20:48

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:58

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 23:20:48

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:58

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 23:20:48

**US3732023**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:28:58**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 23:20:48



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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:58

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered '0'	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 23:20:48

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:58

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered 'I'	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 23:20:48

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:58

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered 'I'	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 23:20:48

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:58

[Outcome](#)

Audit	User	Time (GMT)
Query 'Per CDM RQ: Data is required. Please complete. Thank you' answered with 'pending medical records - as of 26Apr2021 still hospitalized' (Site from DM).	Gordon Bovee (b) (4)	03 May 2021 16:39:43
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	01 May 2021 15:35:15
User opened query 'Per CDM RQ: Data is required. Please complete. Thank you' (Site from DM).	(b) (4), (b) (6)	01 May 2021 11:53:20
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
Query 'Data is required. Please complete.' answered with 'pending medical records - as of 26Apr2021 still hospitalized' (Site from System).	He (Helen) Pu (b) (4)	28 Apr 2021 17:43:31
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Apr 2021 23:20:48
User entered empty.	Linda Vega (b) (4)	26 Apr 2021 23:20:48

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:28:58

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 22:19:26
User entered empty.	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 23:20:48

**US3732023**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:28:58**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered empty.	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 23:20:48

**US3732023**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:28:58**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Apr 2021 23:20:48

**US3732023**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:28:58**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Apr 2021 23:20:48



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:28:58

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:31:44
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	07 Aug 2020 23:19:31

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:28:58

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: MELATONIN RECEPTOR AGONISTS, PRODUCT: MELATONIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	07 Aug 2020 23:21:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 23:21:25
Data point term sent to Coder	System	07 Aug 2020 23:20:24
User entered 'melatonin'	Lauren Arnett (b) (4) (b) (4)	07 Aug 2020 23:20:02

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:28:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'No (N)'	Lauren Arnett (b) (4)	07 Aug 2020 23:20:02
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:28:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'insomnia'	Lauren Arnett (b) (4)	07 Aug 2020 23:20:02
	(b) (4)	

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:28:58**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered '10'	Lauren Arnett (b) (4)	07 Aug 2020 23:20:02
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:28:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'mg (mg)'	Lauren Arnett (b) (4)	07 Aug 2020 23:20:02
	(b) (4)	

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:28:58**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered empty.	Lauren Arnett (b) (4)	07 Aug 2020 23:20:02
	(b) (4)	

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:28:58**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'as needed (PRN)'	Lauren Arnett (b) (4)	07 Aug 2020 23:20:02
	(b) (4)	



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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:28:58**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered empty.	Lauren Arnett (b) (4)	07 Aug 2020 23:20:02
	(b) (4)	

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:28:58**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'Oral (ORAL)'	Lauren Arnett (b) (4)	07 Aug 2020 23:20:02
	(b) (4)	

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:28:58**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered empty.	Lauren Arnett (b) (4)	07 Aug 2020 23:20:02
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:28:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4)	
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ongoing' (Site from System).	(b) (4), (b) (6)	10 Aug 2020 11:42:02
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	Lauren Arnett (b) (4)	07 Aug 2020 23:20:12
User entered 'un UNK 2019'	(b) (4)	
	System	07 Aug 2020 23:20:02
	Lauren Arnett (b) (4)	07 Aug 2020 23:20:02
	(b) (4)	

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:28:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered '0'	Lauren Arnett (b) (4)	07 Aug 2020 23:20:02
	(b) (4)	

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:28:58**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	07 Aug 2020 23:20:02
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:28:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered empty.	Lauren Arnett (b) (4)	07 Aug 2020 23:20:02
	(b) (4)	

US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:28:58**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'No (N)'	Lauren Arnett (b) (4)	07 Aug 2020 23:20:02
	(b) (4)	



**US3732023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:28:58**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 23:20:02

US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:28:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 23:20:02

US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:28:58**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 23:20:02

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:28:58

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Sep 2020 22:53:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Sep 2020 22:53:53
Data point term sent to Coder	System	14 Sep 2020 22:53:05
Coding entries removed.	Lauren Arnett (b) (4)	14 Sep 2020 22:52:41
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Aug 2020 17:37:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Aug 2020 17:37:12
Data point term sent to Coder	System	17 Aug 2020 17:36:21
User entered 'flonase'	Lauren Arnett (b) (4)	17 Aug 2020 17:35:28

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:28:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'No (N)'	Lauren Arnett (b) (4)	17 Aug 2020 17:35:28
	(b) (4)	

**US3732023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:28:58**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'seasonal allergies'	Lauren Arnett (b) (4)	17 Aug 2020 17:35:28
	(b) (4)	

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:28:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered '50'	Lauren Arnett (b) (4)	17 Aug 2020 17:35:28
	(b) (4)	

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:28:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User closed query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication. Please correct the unit as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 11:29:05
Query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication. Please correct the unit as appropriate.' answered with 'data is updated ' (Site from DM).	Amara Yilmaz (b) (4)	28 Sep 2020 19:50:05
User entered 'ug (ug)' reason for change: Data Entry Error	Amara Yilmaz (b) (4)	28 Sep 2020 19:49:56
User opened query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication. Please correct the unit as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 11:25:25
User entered 'mg (mg)'	Lauren Arnett (b) (4)	17 Aug 2020 17:35:28



US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:28:58**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered empty.	Lauren Arnett (b) (4)	17 Aug 2020 17:35:28
	(b) (4)	

US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:28:58**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'as needed (PRN)'	Lauren Arnett (b) (4)	17 Aug 2020 17:35:28
	(b) (4)	

US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:28:58**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered empty.	Lauren Arnett (b) (4)	17 Aug 2020 17:35:28
	(b) (4)	

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:28:58

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User closed query 'Per MM, Please review the route of administration and confirm/update as necessary' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 19:38:43
Query 'Per MM, Please review the route of administration and confirm/update as necessary' answered with 'updated' (Site from DM).	Lauren Arnett (b) (4)	14 Sep 2020 22:52:48
User entered 'Nasal (NASAL)' reason for change: New Information	Lauren Arnett (b) (4)	14 Sep 2020 22:52:41
User opened query 'Per MM, Please review the route of administration and confirm/update as necessary' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 23:08:03
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Lauren Arnett (b) (4)	17 Aug 2020 17:35:28

US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:28:58**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered empty.	Lauren Arnett (b) (4)	17 Aug 2020 17:35:28
	(b) (4)	

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:28:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4)	18 Aug 2020 12:15:11
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ongoing' (Site from System).	(b) (4), (b) (6)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	Lauren Arnett (b) (4)	17 Aug 2020 17:35:41
User entered 'un UNK 2018'	(b) (4)	
	System	17 Aug 2020 17:35:28
	Lauren Arnett (b) (4)	17 Aug 2020 17:35:28
	(b) (4)	

US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:28:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered '0'	Lauren Arnett (b) (4)	17 Aug 2020 17:35:28
	(b) (4)	

**US3732023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:28:58**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	17 Aug 2020 17:35:28
	(b) (4)	



US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:28:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered empty.	Lauren Arnett (b) (4)	17 Aug 2020 17:35:28
	(b) (4)	

US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:28:58**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'No (N)'	Lauren Arnett (b) (4)	17 Aug 2020 17:35:28
	(b) (4)	

**US3732023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:28:58**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 17:35:28

US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:28:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 17:35:28

US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:28:58**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 17:35:28

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:28:58

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User coded data point as ATC: VARIOUS, ATC: HOMEOPATHIC PREPARATION, PRODUCT: HERBAL EXTRACT NOS;HOMEOPATHICS NOS, PRODUCTSYNONYM: SIMILASAN - version WHODrug-Global-B3\\202003.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Aug 2020 16:23:42
Data point term sent to Coder User entered 'similasan'	(b) (4)	
	Coder Import (b) (4)	24 Aug 2020 16:23:42
	(b) (4)	
	System	24 Aug 2020 16:22:49
	Lauren Arnett (b) (4)	24 Aug 2020 16:22:29
	(b) (4)	

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:28:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'No (N)'	Lauren Arnett (b) (4)	24 Aug 2020 16:22:29
	(b) (4)	

US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:28:58**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'seasonal allergies'	Lauren Arnett (b) (4)	24 Aug 2020 16:22:29
	(b) (4)	



US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:28:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered '1'	Lauren Arnett (b) (4)	24 Aug 2020 16:22:29
	(b) (4)	

US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:28:58**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'Other (OTHER)'	Lauren Arnett (b) (4)	24 Aug 2020 16:22:29
	(b) (4)	

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:28:58

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'drop'	Lauren Arnett (b) (4)	24 Aug 2020 16:22:29
	(b) (4)	

US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:28:58**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'as needed (PRN)'	Lauren Arnett (b) (4)	24 Aug 2020 16:22:29
	(b) (4)	

US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:28:58**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered empty.	Lauren Arnett (b) (4)	24 Aug 2020 16:22:29
	(b) (4)	

US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:28:58**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'Intraocular (INTRAOCULAR)'	(b) (4) Lauren Arnett (b) (4) (b) (4)	24 Aug 2020 16:22:29

US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:28:58**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered empty.	Lauren Arnett (b) (4)	24 Aug 2020 16:22:29
	(b) (4)	

US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:28:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'un UNK 2020'	Lauren Arnett (b) (4)	24 Aug 2020 16:22:29
	(b) (4)	



US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:28:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered '0'	Lauren Arnett (b) (4)	24 Aug 2020 16:22:29
	(b) (4)	

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:28:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	24 Aug 2020 16:22:29
	(b) (4)	

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:28:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered empty.	Lauren Arnett (b) (4)	24 Aug 2020 16:22:29
	(b) (4)	

US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:28:58**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'No (N)'	Lauren Arnett (b) (4)	24 Aug 2020 16:22:29
	(b) (4)	

**US3732023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:28:58**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 16:22:29

US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:28:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 16:22:29

**US3732023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:28:58**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 16:22:29

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:28:58

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	24 Aug 2020 21:59:34
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 Aug 2020 21:59:34
Data point term sent to Coder	System	24 Aug 2020 16:23:51
User entered 'aspirin'	Lauren Arnett (b) (4) (b) (4)	24 Aug 2020 16:23:12



US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:28:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'No (N)'	Lauren Arnett (b) (4)	24 Aug 2020 16:23:12
	(b) (4)	

US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:28:58**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'non-migraine headaches, and back pain'	Lauren Arnett (b) (4)	24 Aug 2020 16:23:12
	(b) (4)	

US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:28:58**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered '325'	Lauren Arnett (b) (4)	24 Aug 2020 16:23:12
	(b) (4)	

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:28:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'mg (mg)'	Lauren Arnett (b) (4)	24 Aug 2020 16:23:12
	(b) (4)	

US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:28:58**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered empty.	Lauren Arnett (b) (4)	24 Aug 2020 16:23:12
	(b) (4)	

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:28:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'as needed (PRN)'	Lauren Arnett (b) (4)	24 Aug 2020 16:23:12
	(b) (4)	

US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:28:58**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered empty.	Lauren Arnett (b) (4)	24 Aug 2020 16:23:12
	(b) (4)	

US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:28:58**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'Oral (ORAL)'	Lauren Arnett (b) (4)	24 Aug 2020 16:23:12
	(b) (4)	



US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:28:58**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered empty.	Lauren Arnett (b) (4)	24 Aug 2020 16:23:12
	(b) (4)	

US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:28:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'un UNK 2020'	Lauren Arnett (b) (4)	24 Aug 2020 16:23:12
	(b) (4)	

US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:28:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered '0'	Lauren Arnett (b) (4)	24 Aug 2020 16:23:12
	(b) (4)	

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:28:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	24 Aug 2020 16:23:12
	(b) (4)	

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:28:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered empty.	Lauren Arnett (b) (4)	24 Aug 2020 16:23:12
	(b) (4)	

US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:28:58**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'No (N)'	Lauren Arnett (b) (4)	24 Aug 2020 16:23:12
	(b) (4)	

**US3732023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:28:58**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 16:23:12

**US3732023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:28:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 16:23:12



US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:28:58**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 16:23:12

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:28:58

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	24 Aug 2020 16:26:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 16:26:45
Data point term sent to Coder	System	24 Aug 2020 16:25:56
User entered 'Tylenol'	Lauren Arnett (b) (4) (b) (4)	24 Aug 2020 16:25:30

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:28:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'No (N)'	Lauren Arnett (b) (4)	24 Aug 2020 16:25:30
	(b) (4)	

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:28:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'non-migraine headaches and back pain'	(b) (4) Lauren Arnett (b) (4)	24 Aug 2020 16:25:30
	(b) (4)	

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:28:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered '500'	Lauren Arnett (b) (4)	24 Aug 2020 16:25:30
	(b) (4)	

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:28:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'mg (mg)'	Lauren Arnett (b) (4)	24 Aug 2020 16:25:30
	(b) (4)	

US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:28:58**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered empty.	Lauren Arnett (b) (4)	24 Aug 2020 16:25:30
	(b) (4)	

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:28:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'as needed (PRN)'	Lauren Arnett (b) (4)	24 Aug 2020 16:25:30
	(b) (4)	



US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:28:58

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered empty.	Lauren Arnett (b) (4)	24 Aug 2020 16:25:30
	(b) (4)	

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:28:58

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'Oral (ORAL)'	Lauren Arnett (b) (4)	24 Aug 2020 16:25:30
	(b) (4)	

US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:28:58**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered empty.	Lauren Arnett (b) (4)	24 Aug 2020 16:25:30
	(b) (4)	

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:28:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'un UNK 2015'	Lauren Arnett (b) (4)	24 Aug 2020 16:25:30
	(b) (4)	

US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:28:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered '0'	Lauren Arnett (b) (4)	24 Aug 2020 16:25:30
	(b) (4)	

US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:28:58**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	24 Aug 2020 16:25:30
	(b) (4)	

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:28:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered empty.	Lauren Arnett (b) (4)	24 Aug 2020 16:25:30
	(b) (4)	

US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:28:58**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'No (N)'	Lauren Arnett (b) (4)	24 Aug 2020 16:25:30
	(b) (4)	



**US3732023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:28:58**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 16:25:30

US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:28:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 16:25:30

**US3732023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:28:58**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 16:25:30

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:28:58

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:48:28
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Dec 2020 17:31:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Dec 2020 17:31:00
Data point term sent to Coder	System	09 Dec 2020 17:29:34
User entered 'flu vaccine'	Amara Yilmaz (b) (4)	09 Dec 2020 17:29:09

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:28:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:48:28
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'Yes (Y)'	Amara Yilmaz (b) (4)	09 Dec 2020 17:29:09

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:28:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:48:28
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'influenza'	Amara Yilmaz (b) (4)	09 Dec 2020 17:29:09

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:28:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:48:28
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered '0.5'	Amara Yilmaz (b) (4)	09 Dec 2020 17:29:09

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:28:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:48:28
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'mL (mL)'	Amara Yilmaz (b) (4)	09 Dec 2020 17:29:09



US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:28:58

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:48:28
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered empty.	Amara Yilmaz (b) (4)	09 Dec 2020 17:29:09

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:28:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:48:28
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'once (ONCE)'	Amara Yilmaz (b) (4)	09 Dec 2020 17:29:09

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:28:58

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:48:28
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered empty.	Amara Yilmaz (b) (4)	09 Dec 2020 17:29:09

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:28:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:48:28
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'Intramuscular (INTRAMUSCULAR)'	Amara Yilmaz (b) (4)	09 Dec 2020 17:29:09

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:28:58

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:48:28
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered empty.	Amara Yilmaz (b) (4)	09 Dec 2020 17:29:09

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:28:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:48:28
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered '05 Nov 2020'	Amara Yilmaz (b) (4)	09 Dec 2020 17:29:09

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:28:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:48:28
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered '0'	Amara Yilmaz (b) (4)	09 Dec 2020 17:29:09

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:28:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:48:28
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'No (N)'	Amara Yilmaz (b) (4)	09 Dec 2020 17:29:09



US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:28:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:48:28
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered '05 Nov 2020'	Amara Yilmaz (b) (4)	09 Dec 2020 17:29:09

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:28:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:48:28
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'No (N)'	Amara Yilmaz (b) (4)	09 Dec 2020 17:29:09

US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:28:58**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:48:28
User entered empty.	System	09 Dec 2020 17:29:09

US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:28:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:48:28
User entered empty.	System	09 Dec 2020 17:29:09

US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:28:58**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:48:28
User entered empty.	System	09 Dec 2020 17:29:09

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:28:58

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: FOLIC ACID AND DERIVATIVES, PRODUCT: CALCIUM LEVOMEFOLATE, PRODUCTSYNONYM: METHYL FOLATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	04 Jan 2021 18:59:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Jan 2021 18:59:30
Data point term sent to Coder	System	04 Jan 2021 18:58:30
User entered 'methyl folate'	Amara Yilmaz (b) (4) (b) (4)	04 Jan 2021 18:58:16

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:28:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'Yes (Y)'	Amara Yilmaz (b) (4)	04 Jan 2021 18:58:16
	(b) (4)	

**US3732023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:28:58**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'vitamin deficiency'	(b) (4) Amara Yilmaz (b) (4) (b) (4)	04 Jan 2021 18:58:16



US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:28:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered '400'	(b) (4) Amara Yilmaz (b) (4) (b) (4)	04 Jan 2021 18:58:16

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:28:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'ug (ug)'	Amara Yilmaz (b) (4)	04 Jan 2021 18:58:16
	(b) (4)	

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:28:58

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered empty.	Amara Yilmaz (b) (4)	04 Jan 2021 18:58:16
	(b) (4)	

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:28:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'once daily (QD)'	Amara Yilmaz (b) (4)	04 Jan 2021 18:58:16
	(b) (4)	

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:28:58

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered empty.	Amara Yilmaz (b) (4)	04 Jan 2021 18:58:16
	(b) (4)	

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:28:58

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'Oral (ORAL)'	Amara Yilmaz (b) (4)	04 Jan 2021 18:58:16
	(b) (4)	

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:28:58

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered empty.	Amara Yilmaz (b) (4)	04 Jan 2021 18:58:16
	(b) (4)	

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:28:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered '20 Dec 2020'	Amara Yilmaz (b) (4)	04 Jan 2021 18:58:16
	(b) (4)	



US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:28:58

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered '0'	Amara Yilmaz (b) (4)	04 Jan 2021 18:58:16
	(b) (4)	

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:28:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'Yes (Y)'	Amara Yilmaz (b) (4)	04 Jan 2021 18:58:16
	(b) (4)	

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:28:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered empty.	Amara Yilmaz (b) (4)	04 Jan 2021 18:58:16
	(b) (4)	

US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:28:58**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'No (N)'	(b) (4) Amara Yilmaz (b) (4) (b) (4)	04 Jan 2021 18:58:16

**US3732023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:28:58**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Jan 2021 18:58:16

**US3732023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:28:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Jan 2021 18:58:16

**US3732023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:28:58**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Jan 2021 18:58:16

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:28:58

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
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)	05 Jan 2021 19:30:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 19:30:42
Data point term sent to Coder	System	04 Jan 2021 18:59:31
User entered 'magnesium'	Amara Yilmaz (b) (4) (b) (4)	04 Jan 2021 18:59:17



US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:28:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'Yes (Y)'	Amara Yilmaz (b) (4)	04 Jan 2021 18:59:17
	(b) (4)	

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:28:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'magnesium deficiency'	(b) (4) Amara Yilmaz (b) (4) (b) (4)	04 Jan 2021 18:59:17

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:28:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered '400'	(b) (4) Amara Yilmaz (b) (4) (b) (4)	04 Jan 2021 18:59:17

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:28:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'mg (mg)'	Amara Yilmaz (b) (4)	04 Jan 2021 18:59:17
	(b) (4)	

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:28:58

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered empty.	Amara Yilmaz (b) (4)	04 Jan 2021 18:59:17
	(b) (4)	

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:28:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'once daily (QD)'	Amara Yilmaz (b) (4)	04 Jan 2021 18:59:17
	(b) (4)	

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:28:58

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered empty.	(b) (4) Amara Yilmaz (b) (4) (b) (4)	04 Jan 2021 18:59:17

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:28:58

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'Oral (ORAL)'	Amara Yilmaz (b) (4)	04 Jan 2021 18:59:17
	(b) (4)	



US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:28:58**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered empty.	(b) (4) Amara Yilmaz (b) (4) (b) (4)	04 Jan 2021 18:59:17

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:28:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered '20 Dec 2020'	Amara Yilmaz (b) (4)	04 Jan 2021 18:59:17
	(b) (4)	

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:28:58

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered '0'	Amara Yilmaz (b) (4)	04 Jan 2021 18:59:17
	(b) (4)	

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:28:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'Yes (Y)'	(b) (4) Amara Yilmaz (b) (4) (b) (4)	04 Jan 2021 18:59:17

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:28:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered empty.	Amara Yilmaz (b) (4)	04 Jan 2021 18:59:17
	(b) (4)	

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:28:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'No (N)'	(b) (4) Amara Yilmaz (b) (4) (b) (4)	04 Jan 2021 18:59:17

**US3732023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:28:58**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Jan 2021 18:59:17

US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:28:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Jan 2021 18:59:17



**US3732023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:28:58**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Jan 2021 18:59:17

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:28:58

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, PRODUCT: PYRIDOXINE HYDROCHLORIDE, PRODUCTSYNONYM: VITAMIN B6 - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	04 Jan 2021 19:01:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Jan 2021 19:01:30
Data point term sent to Coder	System	04 Jan 2021 19:00:32
User entered 'vitamin B6'	Amara Yilmaz (b) (4) (b) (4)	04 Jan 2021 19:00:12

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:28:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'Yes (Y)'	Amara Yilmaz (b) (4)	04 Jan 2021 19:00:12
	(b) (4)	

**US3732023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:28:58**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'vitamin deficiency'	(b) (4) Amara Yilmaz (b) (4) (b) (4)	04 Jan 2021 19:00:12

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:28:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered '25'	(b) (4) Amara Yilmaz (b) (4) (b) (4)	04 Jan 2021 19:00:12

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:28:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'mg (mg)'	Amara Yilmaz (b) (4)	04 Jan 2021 19:00:12
	(b) (4)	

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:28:58

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered empty.	Amara Yilmaz (b) (4)	04 Jan 2021 19:00:12
	(b) (4)	

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:28:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'once daily (QD)'	Amara Yilmaz (b) (4)	04 Jan 2021 19:00:12
	(b) (4)	



US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:28:58**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered empty.	Amara Yilmaz (b) (4)	04 Jan 2021 19:00:12
	(b) (4)	

US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:28:58**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'Oral (ORAL)'	Amara Yilmaz (b) (4)	04 Jan 2021 19:00:12
	(b) (4)	

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:28:58

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered empty.	Amara Yilmaz (b) (4)	04 Jan 2021 19:00:12
	(b) (4)	

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:28:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered '20 Dec 2020'	Amara Yilmaz (b) (4)	04 Jan 2021 19:00:12
	(b) (4)	

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:28:58

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered '0'	Amara Yilmaz (b) (4)	04 Jan 2021 19:00:12
	(b) (4)	

**US3732023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:28:58**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'Yes (Y)'	(b) (4) Amara Yilmaz (b) (4) (b) (4)	04 Jan 2021 19:00:12

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:28:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered empty.	Amara Yilmaz (b) (4)	04 Jan 2021 19:00:12
	(b) (4)	

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:28:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'No (N)'	(b) (4) Amara Yilmaz (b) (4) (b) (4)	04 Jan 2021 19:00:12



**US3732023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:28:58**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Jan 2021 19:00:12

**US3732023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:28:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Jan 2021 19:00:12

**US3732023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:28:58**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Jan 2021 19:00:12

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:28:58

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Jan 2021 19:02:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Jan 2021 19:02:30
Data point term sent to Coder	System	04 Jan 2021 19:01:33
User entered 'vitamin b12'	Amara Yilmaz (b) (4)	04 Jan 2021 19:01:03

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:28:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'Yes (Y)'	(b) (4) Amara Yilmaz (b) (4) (b) (4)	04 Jan 2021 19:01:03

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:28:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'vitamin deficiency'	(b) (4) Amara Yilmaz (b) (4) (b) (4)	04 Jan 2021 19:01:03

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:28:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered '1000'	Amara Yilmaz (b) (4)	04 Jan 2021 19:01:03
	(b) (4)	

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:28:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'ug (ug)'	Amara Yilmaz (b) (4)	04 Jan 2021 19:01:03
	(b) (4)	



US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:28:58**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered empty.	(b) (4) Amara Yilmaz (b) (4) (b) (4)	04 Jan 2021 19:01:03

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:28:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'once daily (QD)'	(b) (4) Amara Yilmaz (b) (4) (b) (4)	04 Jan 2021 19:01:03

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:28:58

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered empty.	(b) (4) Amara Yilmaz (b) (4) (b) (4)	04 Jan 2021 19:01:03

US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:28:58**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'Oral (ORAL)'	(b) (4) Amara Yilmaz (b) (4) (b) (4)	04 Jan 2021 19:01:03

US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:28:58**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered empty.	(b) (4) Amara Yilmaz (b) (4) (b) (4)	04 Jan 2021 19:01:03

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:28:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered '20 Dec 2020'	Amara Yilmaz (b) (4)	04 Jan 2021 19:01:03
	(b) (4)	

US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:28:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered '0'	Amara Yilmaz (b) (4)	04 Jan 2021 19:01:03
	(b) (4)	

**US3732023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:28:58**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'Yes (Y)'	(b) (4) Amara Yilmaz (b) (4) (b) (4)	04 Jan 2021 19:01:03



US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:28:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered empty.	Amara Yilmaz (b) (4)	04 Jan 2021 19:01:03
	(b) (4)	

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:28:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'No (N)'	(b) (4) Amara Yilmaz (b) (4) (b) (4)	04 Jan 2021 19:01:03

US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:28:58**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Jan 2021 19:01:03

US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:28:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Jan 2021 19:01:03

US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:28:58**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Jan 2021 19:01:03

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:28:58

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:48:34
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFECTIVES, ATC: FLUOROQUINOLONES, PRODUCT: OFLOXACIN, PRODUCTSYNONYM: OCUFLOX [OFLOXACIN] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Jan 2021 20:24:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 20:24:30
Data point term sent to Coder	System	04 Jan 2021 19:04:36
User entered 'ocuflox 0.3%'	Amara Yilmaz (b) (4) (b) (4)	04 Jan 2021 19:04:28

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:28:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:48:34
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'No (N)'	Amara Yilmaz (b) (4)	04 Jan 2021 19:04:28

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:28:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:48:34
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'right eye cataract surgery'	Amara Yilmaz (b) (4)	04 Jan 2021 19:04:28



US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:28:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:48:34
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'I'	Amara Yilmaz (b) (4)	04 Jan 2021 19:04:28

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:28:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:48:34
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'Other (OTHER)'	Amara Yilmaz (b) (4)	04 Jan 2021 19:04:28

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:28:58

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:48:34
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'drop'	Amara Yilmaz (b) (4)	04 Jan 2021 19:04:28

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:28:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:48:34
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'four times daily (QID)'	Amara Yilmaz (b) (4)	04 Jan 2021 19:04:28

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:28:58

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:48:34
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered empty.	Amara Yilmaz (b) (4)	04 Jan 2021 19:04:28

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:28:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:48:34
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'Intraocular (INTRAOCULAR)'	Amara Yilmaz (b) (4)	04 Jan 2021 19:04:28

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:28:58

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:48:34
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered empty.	Amara Yilmaz (b) (4)	04 Jan 2021 19:04:28

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:28:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:48:34
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered '10 Dec 2020'	Amara Yilmaz (b) (4)	04 Jan 2021 19:04:28



US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:28:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:48:34
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered '0'	Amara Yilmaz (b) (4)	04 Jan 2021 19:04:28

**US3732023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:28:58**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:48:34
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'No (N)'	Amara Yilmaz (b) (4)	04 Jan 2021 19:04:28

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:28:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:48:34
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered '17 Dec 2020'	Amara Yilmaz (b) (4)	04 Jan 2021 19:04:28

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:28:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:48:34
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'No (N)'	Amara Yilmaz (b) (4)	04 Jan 2021 19:04:28

US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:28:58**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:48:34
User entered '4'	System	04 Jan 2021 19:04:28

**US3732023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:28:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:48:34
User entered '1'	System	04 Jan 2021 19:04:28

US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:28:58**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:48:34
User entered '804 (804)'	System	04 Jan 2021 19:04:28

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:28:58

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:48:47
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFLAMMATORY AGENTS, ATC: CORTICOSTEROIDS, PLAIN, PRODUCT: PREDNISONE ACETATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Jan 2021 15:45:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 15:45:45
Data point term sent to Coder	System	04 Jan 2021 19:06:39
User entered 'prednisone acetate 1%'	Amara Yilmaz (b) (4) (b) (4)	04 Jan 2021 19:05:40



US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:28:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:48:47
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'No (N)'	Amara Yilmaz (b) (4)	04 Jan 2021 19:05:40

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:28:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:48:47
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'right eye cataract surgery'	Amara Yilmaz (b) (4)	04 Jan 2021 19:05:40

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:28:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:48:47
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered '4'	Amara Yilmaz (b) (4)	04 Jan 2021 19:05:40

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:28:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:48:47
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'Other (OTHER)'	Amara Yilmaz (b) (4)	04 Jan 2021 19:05:40

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:28:58

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:48:47
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'drop'	Amara Yilmaz (b) (4)	04 Jan 2021 19:05:40

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:28:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:48:47
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'once daily (QD)'	Amara Yilmaz (b) (4)	04 Jan 2021 19:05:40

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:28:58

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:48:47
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered empty.	Amara Yilmaz (b) (4)	04 Jan 2021 19:05:40

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:28:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:48:47
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'Intraocular (INTRAOCULAR)'	Amara Yilmaz (b) (4)	04 Jan 2021 19:05:40



US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:28:58

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:48:47
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered empty.	Amara Yilmaz (b) (4)	04 Jan 2021 19:05:40

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:28:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:48:47
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered '10 Dec 2020'	Amara Yilmaz (b) (4)	04 Jan 2021 19:05:40

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:28:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:48:47
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered '0'	Amara Yilmaz (b) (4)	04 Jan 2021 19:05:40

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:28:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:48:47
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'No (N)'	Amara Yilmaz (b) (4)	04 Jan 2021 19:05:40

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:28:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:48:47
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered '17 Dec 2020'	Amara Yilmaz (b) (4)	04 Jan 2021 19:05:40

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:28:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:48:47
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'No (N)'	Amara Yilmaz (b) (4)	04 Jan 2021 19:05:40

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:28:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:48:47
User entered '1'	System	04 Jan 2021 19:05:40

**US3732023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:28:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:48:47
User entered '1'	System	04 Jan 2021 19:05:40



**US3732023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:28:58**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:48:47
User entered '804 (804)'	System	04 Jan 2021 19:05:40

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:28:58

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFLAMMATORY AGENTS, ATC: CORTICOSTEROIDS, PLAIN, PRODUCT: PREDNISONE ACETATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Jan 2021 15:45:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 15:45:45
Data point term sent to Coder	System	04 Jan 2021 19:07:39
User entered 'prednisone acetate 1%'	Amara Yilmaz (b) (4) (b) (4)	04 Jan 2021 19:07:01

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:28:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'No (N)'	Amara Yilmaz (b) (4)	04 Jan 2021 19:07:01
	(b) (4)	

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:28:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'right eye cataract surgery'	(b) (4) Amara Yilmaz (b) (4) (b) (4)	04 Jan 2021 19:07:01

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:28:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered '2'	(b) (4) Amara Yilmaz (b) (4) (b) (4)	04 Jan 2021 19:07:01

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:28:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'Other (OTHER)'	Amara Yilmaz (b) (4)	04 Jan 2021 19:07:01
	(b) (4)	

US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:28:58**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'drops'	Amara Yilmaz (b) (4)	04 Jan 2021 19:07:01
	(b) (4)	

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:28:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'once daily (QD)'	(b) (4) Amara Yilmaz (b) (4) (b) (4)	04 Jan 2021 19:07:01



US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:28:58

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered empty.	(b) (4) Amara Yilmaz (b) (4) (b) (4)	04 Jan 2021 19:07:01

US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:28:58**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'Intraocular (INTRAOCULAR)'	(b) (4) Amara Yilmaz (b) (4) (b) (4)	04 Jan 2021 19:07:01

US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:28:58**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered empty.	(b) (4) Amara Yilmaz (b) (4) (b) (4)	04 Jan 2021 19:07:01

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:28:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User closed query 'Per DM CLR: Please review the start date of this medication as it overlaps with PREDNISONE ACETATE 1% CM#12 / (Start date 10 DEC 2020 - Stop date 17 DEC 2020). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 07:58:10
Query 'Per DM CLR: Please review the start date of this medication as it overlaps with PREDNISONE ACETATE 1% CM#12 / (Start date 10 DEC 2020 - Stop date 17 DEC 2020). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' answered with 'correct as is. Dosage has decreased. Change in dosage was recorded ' (Site from DM).	Gordon Bovee (b) (4)	04 Feb 2021 18:51:08
User opened query 'Per DM CLR: Please review the start date of this medication as it overlaps with PREDNISONE ACETATE 1% CM#12 / (Start date 10 DEC 2020 - Stop date 17 DEC 2020). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 11:41:56
Query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with PREDNISONE ACETATE 1% CM#12 / (Start date 10 DEC 2020 - Stop date 17 DEC 2020). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' canceled (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 11:41:44
User opened query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with PREDNISONE ACETATE 1% CM#12 / (Start date 10 DEC 2020 - Stop date 17 DEC 2020). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 11:41:36
User entered '17 Dec 2020'	Amara Yilmaz (b) (4)	04 Jan 2021 19:07:01

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:28:58

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered '0'	Amara Yilmaz (b) (4)	04 Jan 2021 19:07:01
	(b) (4)	

**US3732023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:28:58**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'Yes (Y)'	(b) (4) Amara Yilmaz (b) (4) (b) (4)	04 Jan 2021 19:07:01

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:28:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered empty.	(b) (4) Amara Yilmaz (b) (4) (b) (4)	04 Jan 2021 19:07:01

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:28:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'No (N)'	(b) (4) Amara Yilmaz (b) (4) (b) (4)	04 Jan 2021 19:07:01



**US3732023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:28:58**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Jan 2021 19:07:01

US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:28:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Jan 2021 19:07:01

**US3732023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:28:58**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Jan 2021 19:07:01

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:28:58

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFLAMMATORY AGENTS, ATC: CORTICOSTEROIDS, PLAIN, PRODUCT: PREDNISONE ACETATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	16 Mar 2021 09:58:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 09:58:49
Data point term sent to Coder	System	15 Mar 2021 17:46:35
User entered 'Prednisone Acetate 1%'	Gordon Bovee (b) (4) (b) (4)	15 Mar 2021 17:46:30

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:28:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
	(b) (4)	
User entered 'No (N)'	Gordon Bovee (b) (4)	15 Mar 2021 17:46:30
	(b) (4)	

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:28:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
User entered 'Left eye cataract surgery'	(b) (4) Gordon Bovee (b) (4) (b) (4)	15 Mar 2021 17:46:30

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:28:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
User entered '2'	(b) (4) Gordon Bovee (b) (4)	15 Mar 2021 17:46:30
	(b) (4)	

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:28:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
User entered 'Other (OTHER)'	(b) (4) Gordon Bovee (b) (4)	15 Mar 2021 17:46:30
	(b) (4)	



US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:28:58**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
	(b) (4)	
User entered 'drops'	Gordon Bovee (b) (4)	15 Mar 2021 17:46:30
	(b) (4)	

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:28:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
	(b) (4)	
User entered 'once daily (QD)'	Gordon Bovee (b) (4)	15 Mar 2021 17:46:30
	(b) (4)	

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:28:58

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
	(b) (4)	
User entered empty.	Gordon Bovee (b) (4)	15 Mar 2021 17:46:30
	(b) (4)	

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:28:58

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
User entered 'Intraocular (INTRAOCULAR)'	(b) (4) Gordon Bovee (b) (4)	15 Mar 2021 17:46:30

US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:28:58**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
	(b) (4)	
User entered empty.	Gordon Bovee (b) (4)	15 Mar 2021 17:46:30
	(b) (4)	

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:28:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
	(b) (4)	
User entered '25 Feb 2021'	Gordon Bovee (b) (4)	15 Mar 2021 17:46:30
	(b) (4)	

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:28:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
	(b) (4)	
User entered '0'	Gordon Bovee (b) (4)	15 Mar 2021 17:46:30
	(b) (4)	

**US3732023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:28:58**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
	(b) (4)	
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	15 Mar 2021 17:46:30
	(b) (4)	



US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:28:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
User entered empty.	(b) (4) Gordon Bovee (b) (4)	15 Mar 2021 17:46:30
	(b) (4)	

US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:28:58**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
User entered 'No (N)'	(b) (4) Gordon Bovee (b) (4)	15 Mar 2021 17:46:30
	(b) (4)	

**US3732023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:28:58**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Mar 2021 17:46:30

**US3732023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:28:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Mar 2021 17:46:30

**US3732023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:28:58**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Mar 2021 17:46:30

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:28:58

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
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: IBUPROFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	26 Apr 2021 22:40:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Apr 2021 22:40:54
Data point term sent to Coder	System	26 Apr 2021 21:23:51
User entered 'ibuprofen'	Linda Vega (b) (4) (b) (4)	26 Apr 2021 21:23:01

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:28:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
	(b) (4)	
User entered 'No (N)'	Linda Vega (b) (4)	26 Apr 2021 21:23:01
	(b) (4)	

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:28:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered 'left hip pinched nerve'	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 21:23:01



US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:28:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered '600'	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 21:23:01

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:28:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered 'mg (mg)'	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 21:23:01

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:28:58

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered empty.	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 21:23:01

**US3732023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:28:58**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered 'as needed (PRN)'	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 21:23:01

US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:28:58**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered empty.	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 21:23:01

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:28:58

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
	(b) (4)	
User entered 'Oral (ORAL)'	Linda Vega (b) (4)	26 Apr 2021 21:23:01
	(b) (4)	

US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:28:58**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered empty.	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 21:23:01

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:28:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered '16 Apr 2021'	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 21:23:01



US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:28:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered '0'	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 21:23:01

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:28:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered 'Yes (Y)'	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 21:23:01

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:28:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered empty.	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 21:23:01

US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:28:58**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered 'No (N)'	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 21:23:01

**US3732023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:28:58**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Apr 2021 21:23:01

US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:28:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Apr 2021 21:23:01

US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:28:58**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Apr 2021 21:23:01

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:28:58

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: BACLOFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	27 Apr 2021 00:18:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Apr 2021 00:18:55
Data point term sent to Coder	System	26 Apr 2021 23:24:16
User entered 'baclofen'	Linda Vega (b) (4) (b) (4)	26 Apr 2021 23:24:04



US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:28:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
	(b) (4)	
User entered 'No (N)'	Linda Vega (b) (4)	26 Apr 2021 23:24:04
	(b) (4)	

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:28:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered 'left hip pinched nerve'	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 23:24:04

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:28:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered '5'	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 23:24:04

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:28:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered 'mg (mg)'	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 23:24:04

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:28:58

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered empty.	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 23:24:04

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:28:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
	(b) (4)	
User entered 'three times daily (TID)'	Linda Vega (b) (4)	26 Apr 2021 23:24:04
	(b) (4)	

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:28:58

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	28 Apr 2021 22:19:26
User entered empty.	Linda Vega (b) (4) (b) (4)	26 Apr 2021 23:24:04

US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:28:58**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
	(b) (4)	
User entered 'Oral (ORAL)'	Linda Vega (b) (4)	26 Apr 2021 23:24:04
	(b) (4)	



US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:28:58**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered empty.	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 23:24:04

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:28:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered '16 Apr 2021'	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 23:24:04

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:28:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered '0'	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 23:24:04

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:28:58

[Ongoing?](#)

Audit	User	Time (GMT)
Signature has been broken.	Linda Vega (b) (4)	03 May 2021 22:03:28
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Linda Vega (b) (4)	03 May 2021 22:03:28
	(b) (4)	
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
	(b) (4)	
User entered 'Yes (Y)'	Linda Vega (b) (4)	26 Apr 2021 23:24:04
	(b) (4)	

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:28:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Signature has been broken.	Linda Vega (b) (4)	03 May 2021 22:03:28
	(b) (4)	
User entered '23 Apr 2021' reason for change: Data Entry Error	Linda Vega (b) (4)	03 May 2021 22:03:28
	(b) (4)	
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
	(b) (4)	
User entered empty.	Linda Vega (b) (4)	26 Apr 2021 23:24:04
	(b) (4)	

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:28:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Apr 2021 23:29:18
User entered 'No (N)' reason for change: Data Entry Error	System	26 Apr 2021 23:29:18
User opened query 'Data is required. Please complete.' (Site from System).	Linda Vega (b) (4)	26 Apr 2021 23:29:18
User entered empty.	(b) (4)	
	System	26 Apr 2021 23:24:04
	Linda Vega (b) (4)	26 Apr 2021 23:24:04
	(b) (4)	

**US3732023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:28:58**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	26 Apr 2021 23:24:04

US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:28:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Apr 2021 23:24:04



**US3732023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:28:58**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Apr 2021 23:24:04

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:28:58

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN, PRODUCTSYNONYM: NEURONTIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	27 Apr 2021 00:08:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Apr 2021 00:08:09
Data point term sent to Coder	System	26 Apr 2021 23:31:18
User entered 'neurontin'	Linda Vega (b) (4) (b) (4)	26 Apr 2021 23:30:24

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:28:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Apr 2021 20:49:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Apr 2021 20:49:25
User entered 'No (N)' reason for change: Data Entry Error	Linda Vega (b) (4)	27 Apr 2021 20:49:25
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Apr 2021 23:30:24
User entered empty.	Linda Vega (b) (4)	26 Apr 2021 23:30:24
	(b) (4)	

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:28:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered 'left hip pinched nerve'	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 23:30:24

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:28:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered '300'	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 23:30:24

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:28:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered 'mg (mg)'	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 23:30:24

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:28:58

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered empty.	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 23:30:24

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:28:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
	(b) (4)	
User entered 'three times daily (TID)'	Linda Vega (b) (4)	26 Apr 2021 23:30:24
	(b) (4)	



US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:28:58

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered empty.	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 23:30:24

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:28:58

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered 'Oral (ORAL)'	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 23:30:24

US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:28:58**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered empty.	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 23:30:24

**US3732023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:28:58**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered '20 Apr 2021'	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 23:30:24

US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:28:58**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered '0'	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 23:30:24

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:28:58

[Ongoing?](#)

Audit	User	Time (GMT)
Signature has been broken.	Linda Vega (b) (4)	03 May 2021 22:27:07
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Linda Vega (b) (4)	03 May 2021 22:27:07
	(b) (4)	
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
	(b) (4)	
User entered 'Yes (Y)'	Linda Vega (b) (4)	26 Apr 2021 23:30:24
	(b) (4)	

US3732023

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:28:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Signature has been broken.	Linda Vega (b) (4)	03 May 2021 22:27:07
	(b) (4)	
User entered '23 Apr 2021' reason for change: Data Entry Error	Linda Vega (b) (4)	03 May 2021 22:27:07
	(b) (4)	
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
	(b) (4)	
User entered empty.	Linda Vega (b) (4)	26 Apr 2021 23:30:24
	(b) (4)	

US3732023

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:28:58**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered 'No (N)'	(b) (4) Linda Vega (b) (4) (b) (4)	26 Apr 2021 23:30:24



**US3732023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:28:58**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	26 Apr 2021 23:30:24

**US3732023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:28:58**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Apr 2021 23:30:24

**US3732023**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:28:58**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Apr 2021 23:30:24

US3732023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:28:58

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:31:44
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'Yes (Y)'	Amara Yilmaz (b) (4)	04 Jan 2021 18:47:21

US3732023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:28:58

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 20:54:37
	(b) (4)	
Signature has been broken.	Sylvia Lindholm (b) (4)	02 Apr 2021 19:02:18
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered '10 Dec 2020'	Amara Yilmaz (b) (4)	04 Jan 2021 18:47:47
	(b) (4)	

US3732023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:28:58

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
User entered 'right CATARACT SURGERY' reason for change: Data Entry Error	(b) (4)	
	Amara Yilmaz (b) (4)	04 Jan 2021 19:07:30
User entered 'cataract surgery'	(b) (4)	
	Amara Yilmaz (b) (4)	04 Jan 2021 18:47:47
	(b) (4)	

US3732023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:28:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered 'Adverse Event (AE)'	Amara Yilmaz (b) (4)	04 Jan 2021 18:47:47
	(b) (4)	

US3732023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:28:58

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 20:54:37
	(b) (4)	
Signature has been broken.	Sylvia Lindholm (b) (4)	02 Apr 2021 19:02:24
User signature succeeded.	Scott Overcash (b) (4)	13 Feb 2021 01:31:48
	(b) (4)	
User entered empty.	Amara Yilmaz (b) (4)	04 Jan 2021 18:47:47
	(b) (4)	



US3732023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:28:58

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:35:26
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
User entered '25 Feb 2021'	(b) (4) Gordon Bovee (b) (4) (b) (4)	15 Mar 2021 17:41:08

US3732023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:28:58

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:35:26
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
User entered 'Left cataract surgery'	(b) (4) Gordon Bovee (b) (4) (b) (4)	15 Mar 2021 17:41:08

US3732023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:28:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:35:26
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
User entered 'Adverse Event (AE)'	Gordon Bovee (b) (4)	15 Mar 2021 17:41:08

US3732023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:28:58

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:35:26
User signature succeeded.	Scott Overcash (b) (4)	31 Mar 2021 22:55:22
User entered empty.	(b) (4) Gordon Bovee (b) (4)	15 Mar 2021 17:41:08

US3732023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:28:58

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:35:29
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 20:54:37
DataPoint activated with code reason code Data required.	(b) (4) Sylvia Lindholm (b) (4)	02 Apr 2021 23:21:37
DataPoint inactivated with code reason code Data not required.	Sylvia Lindholm (b) (4)	02 Apr 2021 19:02:24
User entered '01 Mar 2021'	Sylvia Lindholm (b) (4)	02 Apr 2021 18:56:16

US3732023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:28:58

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:35:29
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 20:54:37
DataPoint activated with code reason code Data required.	(b) (4) Sylvia Lindholm (b) (4)	02 Apr 2021 23:21:37
DataPoint inactivated with code reason code Data not required.	Sylvia Lindholm (b) (4)	02 Apr 2021 19:02:24
User entered 'Mammogram'	Sylvia Lindholm (b) (4)	02 Apr 2021 18:56:16

US3732023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:28:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:35:29
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 20:54:37
User closed query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	(b) (4) System	02 Apr 2021 23:23:22
User opened query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	02 Apr 2021 23:23:16
User entered 'Diagnostic (DIAGNOSTIC)' reason for change: Data Entry Error	Sylvia Lindholm (b) (4)	02 Apr 2021 23:23:16
DataPoint activated with code reason code Data required.	Sylvia Lindholm (b) (4)	02 Apr 2021 23:21:37
DataPoint inactivated with code reason code Data not required.	Sylvia Lindholm (b) (4)	02 Apr 2021 19:02:24
User entered 'Other (OTHER)'	Sylvia Lindholm (b) (4)	02 Apr 2021 18:56:16

US3732023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:28:58

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:35:29
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 20:54:37
User entered empty; reason for change Data Entry Error	(b) (4) Sylvia Lindholm (b) (4)	02 Apr 2021 23:23:22
DataPoint activated with code reason code Data required.	Sylvia Lindholm (b) (4)	02 Apr 2021 23:21:37
DataPoint inactivated with code reason code Data not required.	Sylvia Lindholm (b) (4)	02 Apr 2021 19:02:24
User entered 'General Health'	Sylvia Lindholm (b) (4)	02 Apr 2021 18:56:16



US3732023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:28:58

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:35:33
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 20:54:37
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	02 Apr 2021 23:23:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Apr 2021 23:23:03
User entered '23 Mar 2021' reason for change: Data Entry Error	Sylvia Lindholm (b) (4)	02 Apr 2021 23:23:03
DataPoint activated with code reason code Data required.	Sylvia Lindholm (b) (4)	02 Apr 2021 23:21:57
DataPoint inactivated with code reason code Data not required.	Sylvia Lindholm (b) (4)	02 Apr 2021 19:02:18
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Apr 2021 19:00:27
User entered empty.	Sylvia Lindholm (b) (4)	02 Apr 2021 19:00:27

US3732023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:28:58

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:35:33
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 20:54:37
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	02 Apr 2021 23:23:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Apr 2021 23:23:03
User entered 'Ultrasound' reason for change: Data Entry Error	Sylvia Lindholm (b) (4)	02 Apr 2021 23:23:03
DataPoint activated with code reason code Data required.	Sylvia Lindholm (b) (4)	02 Apr 2021 23:21:57
DataPoint inactivated with code reason code Data not required.	Sylvia Lindholm (b) (4)	02 Apr 2021 19:02:18
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Apr 2021 19:00:27
User entered empty.	Sylvia Lindholm (b) (4)	02 Apr 2021 19:00:27

US3732023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:28:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:35:33
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 20:54:37
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Apr 2021 23:23:03
User entered 'Diagnostic (DIAGNOSTIC)' reason for change: Data Entry Error	Sylvia Lindholm (b) (4)	02 Apr 2021 23:23:03
DataPoint activated with code reason code Data required.	Sylvia Lindholm (b) (4)	02 Apr 2021 23:21:57
DataPoint inactivated with code reason code Data not required.	Sylvia Lindholm (b) (4)	02 Apr 2021 19:02:18
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Apr 2021 19:00:27
User entered empty.	Sylvia Lindholm (b) (4)	02 Apr 2021 19:00:27

US3732023

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:28:58

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:35:33
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 20:54:37
DataPoint activated with code reason code Data required.	(b) (4) Sylvia Lindholm (b) (4)	02 Apr 2021 23:21:57
DataPoint inactivated with code reason code Data not required.	Sylvia Lindholm (b) (4)	02 Apr 2021 19:02:18
User entered empty.	Sylvia Lindholm (b) (4)	02 Apr 2021 19:00:27

**US3732023**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:58**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	27 Apr 2021 14:02:38
User entered 'USA-US102-2021-MRNA-1273-P301000009'	System	27 Apr 2021 14:02:19

**US3732023**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:58**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
Reviewed for Safety.	(b) (4)	(b) (4)
	(b) (4), (b) (6)	27 Apr 2021 14:02:38
User entered 'Yes (Y)'	System	27 Apr 2021 14:02:19

**US3732023**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:58**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	27 Apr 2021 14:02:38
User entered 'No (N)'	System	27 Apr 2021 14:02:19

**US3732023**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:58**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	27 Apr 2021 14:02:38
User entered 'No (N)'	System	27 Apr 2021 14:02:19



**US3732023**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:58**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	27 Apr 2021 14:02:38
User entered 'Yes (Y)'	System	27 Apr 2021 14:02:19

**US3732023**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:58**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	27 Apr 2021 14:02:38
User entered 'No (N)'	System	27 Apr 2021 14:02:19

**US3732023**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:58**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	27 Apr 2021 14:02:38
User entered 'No (N)'	System	27 Apr 2021 14:02:19

**US3732023**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:58**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 14:02:38
User entered 'No (N)'	System	27 Apr 2021 14:02:19

**US3732023**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:58**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	27 Apr 2021 14:02:38
User entered 'Scott'	System	27 Apr 2021 14:02:19

US3732023

Folder: SAE USA-US102-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	27 Apr 2021 14:02:38
User entered 'Overcash'	System	27 Apr 2021 14:02:19

**US3732023**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:58**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	27 Apr 2021 14:02:38
User entered '5565 Grossmont Center Dr'	System	27 Apr 2021 14:02:19

**US3732023**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:58**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 14:02:38
User entered 'La Mesa'	System	27 Apr 2021 14:02:19



**US3732023**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:58**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	27 Apr 2021 14:02:38
User entered 'CA'	System	27 Apr 2021 14:02:19

**US3732023**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:58**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 14:02:38
User entered '91942'	System	27 Apr 2021 14:02:19

US3732023

Folder: SAE USA-US102-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:58

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered 'US'	(b) (4) System	27 Apr 2021 14:02:45

**US3732023**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:58**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	27 Apr 2021 14:02:45

**US3732023**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:58**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	27 Apr 2021 14:02:38
User entered 'USA-US102-2021-MRNA-1273-P301000009'	System	27 Apr 2021 14:02:19

**US3732023**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:58**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 14:02:38
User entered 'Yes (Y)'	System	27 Apr 2021 14:02:19

**US3732023**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:58**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	27 Apr 2021 14:02:38
User entered 'No (N)'	System	27 Apr 2021 14:02:19

**US3732023**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:58**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
Reviewed for Safety.	(b) (4)	27 Apr 2021 14:02:38
User entered 'No (N)'	(b) (4), (b) (6) System	27 Apr 2021 14:02:19



**US3732023**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:58**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
Reviewed for Safety.	(b) (4)	27 Apr 2021 14:02:38
User entered 'Yes (Y)'	(b) (4), (b) (6) System	27 Apr 2021 14:02:19

**US3732023**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:58**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
Reviewed for Safety.	(b) (4)	(b) (4)
	(b) (4), (b) (6)	27 Apr 2021 14:02:38
User entered 'No (N)'	System	27 Apr 2021 14:02:19

**US3732023**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:58**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	27 Apr 2021 14:02:38
User entered 'No (N)'	System	27 Apr 2021 14:02:19

**US3732023**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:58**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	27 Apr 2021 14:02:38
User entered 'No (N)'	System	27 Apr 2021 14:02:19

**US3732023**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:58**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	27 Apr 2021 14:02:38
User entered 'Scott'	System	27 Apr 2021 14:02:19

**US3732023**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:58**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	27 Apr 2021 14:02:38
User entered 'Overcash'	System	27 Apr 2021 14:02:19

**US3732023**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:58**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	27 Apr 2021 14:02:38
User entered '5565 Grossmont Center Dr'	System	27 Apr 2021 14:02:19

**US3732023**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:58**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	27 Apr 2021 14:02:38
User entered 'La Mesa'	System	27 Apr 2021 14:02:19



**US3732023**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:58**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	27 Apr 2021 14:02:38
User entered 'CA'	System	27 Apr 2021 14:02:19

**US3732023**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:58**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	27 Apr 2021 14:02:38
User entered '91942'	System	27 Apr 2021 14:02:19

US3732023

Folder: SAE USA-US102-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:28:58

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered 'US'	(b) (4) System	27 Apr 2021 14:02:45

**US3732023**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:28:58**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	27 Apr 2021 14:02:45

**US3732023**

**Folder: SAE USA-US102-2021-MRNA-1273-P301000009**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 09:28:58**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	28 Apr 2021 22:19:26
User entered '27/Apr/2021 10:02'	(b) (4) System	27 Apr 2021 14:02:45

US3732023

Folder: SAE USA-US102-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:28:58

**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 22:19:26
User entered 'I'	(b) (4), (b) (6)	27 Apr 2021 14:02:45