

US3162037 (Prod: Advanced Clinical Research - Rancho Paseo - ERN - PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:27:33

All time stamps listed in this document are displayed in GMT

US3162037

Form: Participant Creation

Data signed: (b) (4) 13 Feb 2021 01:34:20

Generated On: 09 Jun 2021 15:27:33

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Participant ID

US3162037

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

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US3162037

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 01:35:18

Generated On: 09 Jun 2021 15:27:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	31 JUL 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

US3162037

Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 01:35:18

Generated On: 09 Jun 2021 15:27:33

Date of Birth (MMM yyyy)	(b) (6) 1952
Age	68
Age Units	YEARS
Age (Derived)	68
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 01:35:18

Generated On: 09 Jun 2021 15:27:33

Date of Informed Consent (*dd MMM yyyy*) 31 JUL 2020

Month and Year of Informed Consent (derived) JUL 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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 01:35:18

Generated On: 09 Jun 2021 15:27:33

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 01:35:18

Generated On: 09 Jun 2021 15:27:33

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 13 Feb 2021 01:35:18

Generated On: 09 Jun 2021 15:27:33

Condition	PENICILLIN ALLERGY
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)	_____



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 13 Feb 2021 01:35:18

Generated On: 09 Jun 2021 15:27:33

Condition	SULFA ALLERGY
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)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 13 Feb 2021 01:35:18

Generated On: 09 Jun 2021 15:27:33

Condition	NATURAL MENOPAUSE
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)	_____

US3162037

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 13 Feb 2021 01:35:18

Generated On: 09 Jun 2021 15:27:33

Condition	ERYTHROMYCIN ALLERGY
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)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 13 Feb 2021 01:35:18

Generated On: 09 Jun 2021 15:27:33

Condition	TETRACYCLINE ALLERGY
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)	

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 13 Feb 2021 01:35:18

Generated On: 09 Jun 2021 15:27:33

Condition	OSTEOPENIA
Start date (dd MMM yyyy)	UN MAR 2018
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)	MAR 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 13 Feb 2021 01:35:18

Generated On: 09 Jun 2021 15:27:33

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 1999
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 1999
Start Year (derived)	1999
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 13 Feb 2021 01:35:18

Generated On: 09 Jun 2021 15:27:33

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN JUN 2018
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)	JUN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 13 Feb 2021 01:35:18

Generated On: 09 Jun 2021 15:27:33

Condition	INTERMITTENT ATRIAL FIBRILLATION
Start date (dd MMM yyyy)	UN MAR 2018
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)	MAR 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 13 Feb 2021 01:35:18

Generated On: 09 Jun 2021 15:27:33

Condition	DEGENERATIVE DISC DISEASE C5, C6, C7
Start date (dd MMM yyyy)	UN MAR 2018
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)	MAR 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 13 Feb 2021 01:35:18

Generated On: 09 Jun 2021 15:27:33

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

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 13 Feb 2021 01:35:18

Generated On: 09 Jun 2021 15:27:33

Condition	RESTLESS LEG SYNDROME, BILATERAL
Start date (dd MMM yyyy)	UN MAY 2018
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)	MAY 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 13 Feb 2021 01:35:18

Generated On: 09 Jun 2021 15:27:33

Condition	LEFT HIP PAIN
Start date (dd MMM yyyy)	UN MAY 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)	MAY 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 13 Feb 2021 01:35:18

Generated On: 09 Jun 2021 15:27:33

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN MAR 2018
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)	MAR 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 13 Feb 2021 01:35:18

Generated On: 09 Jun 2021 15:27:33

Condition	APPENDICITIS
Start date (dd MMM yyyy)	UN UNK 1996
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 1996
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1996
Start Year (derived)	1996
Stop Month and Year (derived)	JAN 1996
Stop Year (derived)	1996

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 13 Feb 2021 01:35:18

Generated On: 09 Jun 2021 15:27:33

Condition	RECURRENT VENTRAL HERNIA
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 (17)

Data signed: (b) (4) 13 Feb 2021 01:35:18

Generated On: 09 Jun 2021 15:27:33

Condition	SMALL BOWEL OBSTRUCTION
Start date (dd MMM yyyy)	UN UNK 1997
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 1997
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1997
Start Year (derived)	1997
Stop Month and Year (derived)	JAN 1997
Stop Year (derived)	1997



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Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 13 Feb 2021 01:35:18

Generated On: 09 Jun 2021 15:27:33

Condition	BILATERAL TINNITUS
Start date (dd MMM yyyy)	UN UNK 1965
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1965
Start Year (derived)	1965
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 13 Feb 2021 01:35:18

Generated On: 09 Jun 2021 15:27:33

Condition	INSOMNIA
Start date (dd MMM yyyy)	UN UNK 1999
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 1999
Start Year (derived)	1999
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 13 Feb 2021 01:35:18

Generated On: 09 Jun 2021 15:27:33

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

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Folder: Screening

Form: Medical History (21)

Data signed: (b) (4) 13 Feb 2021 01:35:18

Generated On: 09 Jun 2021 15:27:33

Condition	RIGHT HIP PAIN
Start date (dd MMM yyyy)	UN FEB 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)	FEB 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 01:35:18

Generated On: 09 Jun 2021 15:27:33

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	31 JUL 2020
Time of assessment ( <i>00:00-23:59</i> )	12:53 (24 HR)
Vital Signs Date and Time (derived)	31 JUL 2020 12:53
Height ( <i>xxx.x</i> )	69 in
Weight ( <i>xxx.x</i> )	177.1 lb
BMI ( <i>xxx.x</i> )	26.20778 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 01:35:18

Generated On: 09 Jun 2021 15:27:33

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

31 JUL 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 01:35:18

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Date of assessment (dd MMM yyyy) 31 JUL 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 2005

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 01:35:18

Generated On: 09 Jun 2021 15:27:33

**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☒ No ☐

**Specify** NONE

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

**No Risk Identified** False

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



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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 01:35:18

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 01:35:18

Generated On: 09 Jun 2021 15:27:33

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

Visit date (dd MMM yyyy)	31 JUL 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT1
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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 01:35:18

Generated On: 09 Jun 2021 15:27:33

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

What was the participant's randomization number? 184328

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) 13 Feb 2021 01:35:18

Generated On: 09 Jun 2021 15:27:33

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 01:35:18

Generated On: 09 Jun 2021 15:27:33

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	31 JUL 2020
Time of assessment (00:00-23:59)	12:53 (24 HR)
Vital Signs Date and Time (derived)	31 JUL 2020 12:53
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)	55 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 01:35:18

Generated On: 09 Jun 2021 15:27:33

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)	31 JUL 2020
Time of assessment (00:00-23:59)	14:46 (24 HR)
Vital Signs Date and Time (derived)	31 JUL 2020 14:46
Temperature (xxx.x)	99.3 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)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 01:35:18

Generated On: 09 Jun 2021 15:27:33

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 01:35:18

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Was study treatment given? Yes ☒  
No ☐

If No, reason not given

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 31 JUL 2020

What was the treatment time? (00:00-23:59) 14:04 (24 HR)

Treatment Date and Time (derived) 31 JUL 2020 14:04

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

What was the frequency of the study treatment dosing? ONCE

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



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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 01:35:18

Generated On: 09 Jun 2021 15:27:33

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	31 JUL 2020
Collection time (00:00-23:59)	13:55 (24 HR)
Collection date and time (derived)	31 JUL 2020 13:55

US3162037

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 01:35:18

Generated On: 09 Jun 2021 15:27:33

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

US3162037

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:35:18

Generated On: 09 Jun 2021 15:27:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162037

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

**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

99.8 °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

31 JUL 2020 15:48

PC Open Date & Time

31 JUL 2020 14:24

PC Close Date & Time

31 JUL 2020 16:54

US3162037

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

**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 98.5 °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	01 AUG 2020 09:23
PC Open Date & Time	31 JUL 2020 17:49
PC Close Date & Time	01 AUG 2020 11:59

US3162037

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 AUG 2020 14:46

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3162037

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:27:33

**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

02 AUG 2020 20:51

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3162037

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:27:33

**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

03 AUG 2020 20:31

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59



US3162037

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 AUG 2020 21:17

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3162037

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:27:33

**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

99.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 AUG 2020 20:52

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3162037

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:27:33

**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.

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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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 AUG 2020 20:46

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3162037

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

31 JUL 2020 15:49

PC Open Date & Time

31 JUL 2020 14:24

PC Close Date & Time

31 JUL 2020 16:54

US3162037

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

01 AUG 2020 09:23

PC Open Date & Time

31 JUL 2020 17:49

PC Close Date & Time

01 AUG 2020 11:59

US3162037

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

01 AUG 2020 14:44

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3162037

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

02 AUG 2020 20:50

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3162037

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

03 AUG 2020 20:28

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59



US3162037

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

04 AUG 2020 21:16

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3162037

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

05 AUG 2020 20:51

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3162037

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

06 AUG 2020 20:44

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3162037

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

**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 ☐

US3162037

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

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

No ☒

Yes ☐

PC Time stamp	31 JUL 2020 15:50
PC Open Date & Time	31 JUL 2020 14:24
PC Close Date & Time	31 JUL 2020 16:54

US3162037

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

**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 ☐

US3162037

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

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

No ☒

Yes ☐

PC Time stamp	01 AUG 2020 09:24
PC Open Date & Time	31 JUL 2020 17:49
PC Close Date & Time	01 AUG 2020 11:59

US3162037

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)



US3162037

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:27:33

Yes <input type="checkbox"/>	
PC Time stamp	01 AUG 2020 14:45
PC Open Date & Time	01 AUG 2020 12:00
PC Close Date & Time	02 AUG 2020 11:59

US3162037

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:27:33

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3162037

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:27:33

Yes <input type="checkbox"/>	
PC Time stamp	02 AUG 2020 20:49
PC Open Date & Time	02 AUG 2020 12:00
PC Close Date & Time	03 AUG 2020 11:59

US3162037

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:27:33

**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 ☒

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EAB) (1725)

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US3162037

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:27:33

Yes <input type="checkbox"/>	
PC Time stamp	03 AUG 2020 20:28
PC Open Date & Time	03 AUG 2020 12:00
PC Close Date & Time	04 AUG 2020 11:59

US3162037

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:27:33

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3162037

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:27:33

Yes <input type="checkbox"/>	
PC Time stamp	04 AUG 2020 21:15
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

US3162037

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:27:33

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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US3162037

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:27:33

Yes <input type="checkbox"/>	
PC Time stamp	05 AUG 2020 20:51
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3162037

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:27:33

TIMEPOINT

DAY 7

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3162037

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:27:33

Yes <input type="checkbox"/>	
PC Time stamp	06 AUG 2020 20:44
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3162037

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

None ☒

**HEADACHE**

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 ☐

PC Time Stamp

07 AUG 2020 20:26

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3162037

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

None ☒

**FATIGUE**

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 07 AUG 2020 20:26

PC Open Date & Time 07 AUG 2020 12:00

PC Close Date & Time 08 AUG 2020 11:59

US3162037

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(8)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your **MUSCLE**

None ☒

**ACHES ALL OVER BODY**

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 07 AUG 2020 20:26

PC Open Date & Time 07 AUG 2020 12:00

PC Close Date & Time 08 AUG 2020 11:59

US3162037

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(8)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

PC Time stamp 07 AUG 2020 20:26

PC Open Date & Time 07 AUG 2020 12:00

PC Close Date & Time 08 AUG 2020 11:59

US3162037

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 15:27:33

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	07 AUG 2020 20:26
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59



US3162037

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:35:18

Generated On: 09 Jun 2021 15:27:33

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 7 AUG 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3162037

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:35:18

Generated On: 09 Jun 2021 15:27:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162037

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:34:21

Generated On: 09 Jun 2021 15:27:33

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3162037

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:34:21

Generated On: 09 Jun 2021 15:27:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162037

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:34:21

Generated On: 09 Jun 2021 15:27:33

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*

US3162037

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:34:21

Generated On: 09 Jun 2021 15:27:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162037

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 01:35:18

Generated On: 09 Jun 2021 15:27:33

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

Visit date (dd MMM yyyy)	28 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT2
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US3162037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 01:35:18

Generated On: 09 Jun 2021 15:27:33

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)	28 AUG 2020
Time of assessment (00:00-23:59)	12:29 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 12:29
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)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG



US3162037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 01:35:18

Generated On: 09 Jun 2021 15:27:33

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)	28 AUG 2020
Time of assessment (00:00-23:59)	14:25 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 14:25
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3162037

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 01:35:18

Generated On: 09 Jun 2021 15:27:33

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 AUG 2020

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

US3162037

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 01:35:18

Generated On: 09 Jun 2021 15:27:33

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) 28 AUG 2020

What was the treatment time? (00:00-23:59) 13:44 (24 HR)

Treatment Date and Time (derived) 28 AUG 2020 13:44

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

US3162037

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 01:35:18

Generated On: 09 Jun 2021 15:27:33

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

Collection date (dd MMM yyyy)	28 AUG 2020
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Collection time (00:00-23:59)	13:17 (24 HR)
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Collection date and time (derived)	28 AUG 2020 13:17
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US3162037

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 01:35:18

Generated On: 09 Jun 2021 15:27:33

Collection date (dd MMM yyyy)			28 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:21	28 AUG 2020 13:21
Nasopharyngeal Swab 2	No		

US3162037

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:35:18

Generated On: 09 Jun 2021 15:27:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162037

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

**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

97.6 °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

28 AUG 2020 14:11

PC Open Date & Time

28 AUG 2020 14:04

PC Close Date & Time

28 AUG 2020 16:34

US3162037

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.6 °F

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

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

PC Time Stamp	28 AUG 2020 21:38
PC Open Date & Time	28 AUG 2020 17:29
PC Close Date & Time	29 AUG 2020 11:59



US3162037

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:27:33

**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

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

29 AUG 2020 20:00

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3162037

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °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

30 AUG 2020 17:29

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3162037

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:27:33

**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

96.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 20:23

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3162037

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.1 °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

01 SEP 2020 19:26

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3162037

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.6 °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

02 SEP 2020 22:22

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3162037

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:27:33

**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

95.7 °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

03 SEP 2020 17:10

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3162037

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

**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

28 AUG 2020 14:11

PC Open Date & Time

28 AUG 2020 14:04

PC Close Date & Time

28 AUG 2020 16:34

US3162037

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

**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

28 AUG 2020 21:38

PC Open Date & Time

28 AUG 2020 17:29

PC Close Date & Time

29 AUG 2020 11:59



US3162037

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:27:33

**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

29 AUG 2020 20:00

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3162037

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:27:33

**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

30 AUG 2020 17:28

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3162037

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:27:33

**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

31 AUG 2020 20:23

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3162037

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:27:33

**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

01 SEP 2020 19:26

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3162037

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:27:33

**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

02 SEP 2020 22:22

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3162037

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:27:33

**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

03 SEP 2020 17:09

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

**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 ☐

US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

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

No ☒

Yes ☐

PC Time stamp	28 AUG 2020 14:12
PC Open Date & Time	28 AUG 2020 14:04
PC Close Date & Time	28 AUG 2020 16:34



US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

**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 ☐

US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

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

No ☒

Yes ☐

PC Time stamp	28 AUG 2020 21:39
PC Open Date & Time	28 AUG 2020 17:29
PC Close Date & Time	29 AUG 2020 11:59

US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:27:33

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 19:59
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:27:33

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:27:33

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 17:28
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:27:33

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 ☒

US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:27:33

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 20:22
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59



US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

DAY 5

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:27:33

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 19:25
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:27:33

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

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US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:27:33

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 22:22
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:27:33

**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 ☒

US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:27:33

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 17:09
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3162037

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:34:21

Generated On: 09 Jun 2021 15:27:33

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 04 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3162037

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:34:21

Generated On: 09 Jun 2021 15:27:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3162037

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:34:21

Generated On: 09 Jun 2021 15:27:33

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 11 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3162037

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:34:21

Generated On: 09 Jun 2021 15:27:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162037

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:35:17

Generated On: 09 Jun 2021 15:27:33

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*

US3162037

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:35:17

Generated On: 09 Jun 2021 15:27:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162037

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 01:35:18

Generated On: 09 Jun 2021 15:27:33

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

Visit date (dd MMM yyyy)	25 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	VISIT3
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US3162037

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 01:35:18

Generated On: 09 Jun 2021 15:27:33

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 SEP 2020
Time of assessment (00:00-23:59)	12:04 (24 HR)
Vital Signs Date and Time (derived)	25 SEP 2020 12:04
Temperature (xxx.x)	36.4 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	11 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	63 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3162037

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 01:35:18

Generated On: 09 Jun 2021 15:27:33

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.*

US3162037

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 01:35:18

Generated On: 09 Jun 2021 15:27:33

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

Collection date (dd MMM yyyy)	25 SEP 2020
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Collection time (00:00-23:59)	12:46 (24 HR)
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Collection date and time (derived)	25 SEP 2020 12:46
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US3162037

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:35:18

Generated On: 09 Jun 2021 15:27:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

<b>TIMEPOINT</b>	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 SEP 2020 19:16:11
Patient Cloud Open Date & Time	30 SEP 2020 00:01
Patient Cloud Close Date & Time	04 OCT 2020 23:59

US3162037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

**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

07 OCT 2020 08:40:46

Patient Cloud Open Date & Time

07 OCT 2020 00:01

Patient Cloud Close Date & Time

11 OCT 2020 23:59

US3162037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

**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

14 OCT 2020 07:48:02

Patient Cloud Open Date & Time

14 OCT 2020 00:01

Patient Cloud Close Date & Time

18 OCT 2020 23:59

US3162037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

**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

28 OCT 2020 10:30:29

Patient Cloud Open Date & Time

28 OCT 2020 00:01

Patient Cloud Close Date & Time

01 NOV 2020 23:59

US3162037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

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	04 NOV 2020 09:27:45
Patient Cloud Open Date & Time	04 NOV 2020 00:01
Patient Cloud Close Date & Time	08 NOV 2020 23:59

US3162037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

**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

11 NOV 2020 10:20:07

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3162037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

DAY 113

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 NOV 2020 19:18:05

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59



US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 NOV 2020 09:03:27
Patient Cloud Open Date & Time	15 NOV 2020 00:01
Patient Cloud Close Date & Time	19 NOV 2020 23:59

US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

**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

22 NOV 2020 08:22:40

Patient Cloud Open Date & Time

22 NOV 2020 00:01

Patient Cloud Close Date & Time

26 NOV 2020 23:59

US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 NOV 2020 09:43:26

Patient Cloud Open Date & Time

29 NOV 2020 00:01

Patient Cloud Close Date & Time

03 DEC 2020 23:59

US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

**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

06 DEC 2020 19:37:04

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

**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

13 DEC 2020 19:12:26

Patient Cloud Open Date & Time

13 DEC 2020 00:01

Patient Cloud Close Date & Time

17 DEC 2020 23:59

US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	20 DEC 2020 10:26:43
Patient Cloud Open Date & Time	20 DEC 2020 00:01
Patient Cloud Close Date & Time	24 DEC 2020 23:59

US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

**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

27 DEC 2020 00:01:45

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

**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

03 JAN 2021 10:18:13

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59



US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 JAN 2021 09:48:01
Patient Cloud Open Date & Time	10 JAN 2021 00:01
Patient Cloud Close Date & Time	14 JAN 2021 23:59

US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

**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

17 JAN 2021 09:53:13

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 JAN 2021 19:32:02
Patient Cloud Open Date & Time	24 JAN 2021 00:01
Patient Cloud Close Date & Time	28 JAN 2021 23:59

US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

**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

31 JAN 2021 09:46:20

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

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	07 FEB 2021 20:03:37
Patient Cloud Open Date & Time	07 FEB 2021 00:01
Patient Cloud Close Date & Time	11 FEB 2021 23:59

US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

<b>TIMEPOINT</b>	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	17 FEB 2021 12:37:32
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

**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

21 FEB 2021 08:28:44

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

**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

28 FEB 2021 19:58:00

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59



US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

<b>TIMEPOINT</b>	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 <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	07 MAR 2021 08:49:55
Patient Cloud Open Date & Time	07 MAR 2021 00:01
Patient Cloud Close Date & Time	11 MAR 2021 23:59

US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

**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

14 MAR 2021 08:49:49

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

<b>TIMEPOINT</b>	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 MAR 2021 11:12:10
Patient Cloud Open Date & Time	21 MAR 2021 00:01
Patient Cloud Close Date & Time	25 MAR 2021 23:59

US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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 type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	True
Chills	False
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	True
Body aches	True
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	True
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
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 checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	28 MAR 2021 10:57:48
Patient Cloud Open Date & Time	28 MAR 2021 00:01
Patient Cloud Close Date & Time	01 APR 2021 23:59

US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

**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

04 APR 2021 08:16:47

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

**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

12 APR 2021 10:24:54

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

<b>TIMEPOINT</b>	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 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	18 APR 2021 19:37:27
Patient Cloud Open Date & Time	18 APR 2021 00:01
Patient Cloud Close Date & Time	22 APR 2021 23:59

US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

**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

26 APR 2021 11:30:55

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59



US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

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

Date and time of submission

02 MAY 2021 00:02:47

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

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"/>

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

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

US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

DAY 306

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

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

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

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

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

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

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 ☐



**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

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

30 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

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US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

**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 ☐

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

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

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	13 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 JUN 2021 23:59

US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

**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 ☐

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

DAY 334

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

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

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

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

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

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

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

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



**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

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

27 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

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"/>

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

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

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[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

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US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

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"/>

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

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

US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

**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 ☐

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

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

US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

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



**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	25 JUL 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 JUL 2021 23:59
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US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

**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 ☐

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

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

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[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

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US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

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

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

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

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[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

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US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

**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 ☐

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

**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 ☐



**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

**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 ☐

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

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

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[Patient Cloud Open Date & Time](#)

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29 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 SEP 2021 23:59

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US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

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

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

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

US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

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

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

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



**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

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

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

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

US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

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 <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"/>

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

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

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[Patient Cloud Close Date & Time](#)

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07 OCT 2021 23:59

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US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

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

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

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

US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

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



**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

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

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[Patient Cloud Open Date & Time](#)

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17 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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21 OCT 2021 23:59

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US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

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

US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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"/>

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

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"/>

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

**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°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 ☐



**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

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

US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

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

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

**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 ☐

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

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

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[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

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US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

**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 ☐



**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

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

US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

**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 ☐

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

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

US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

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

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

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

US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

**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 ☐

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

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

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[Patient Cloud Close Date & Time](#)

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06 JAN 2022 23:59

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US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

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

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[Patient Cloud Open Date & Time](#)

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09 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 JAN 2022 23:59

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US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

**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 ☐

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

DAY 544

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

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

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

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

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

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

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

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

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

**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 ☐

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

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

30 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

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US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

**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 ☐



**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

**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 ☐

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

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

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[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

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US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

**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 ☐

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

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

US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

**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°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 ☐

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

**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 ☐



**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

**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 ☐

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

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

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[Patient Cloud Open Date & Time](#)

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13 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 MAR 2022 23:59

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US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

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"/>

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

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

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

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"/>



**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

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

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[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

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US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

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

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

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

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[Patient Cloud Open Date & Time](#)

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10 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 APR 2022 23:59

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US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

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"/>

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

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

US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

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

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

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



**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

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

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[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

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US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

**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 ☐

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

**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 ☐

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

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"/>



**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

**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 ☐

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

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

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[Patient Cloud Open Date & Time](#)

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05 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 JUN 2022 23:59

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US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

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"/>

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

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

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[Patient Cloud Open Date & Time](#)

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12 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 JUN 2022 23:59

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US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

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

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

**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 ☐



**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

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

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

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

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[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

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US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

**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 ☐

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

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

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[Patient Cloud Open Date & Time](#)

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10 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 JUL 2022 23:59

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US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

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"/>

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

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

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[Patient Cloud Open Date & Time](#)

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17 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 JUL 2022 23:59

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US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

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



**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

**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°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 ☐

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

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"/>

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

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

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

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

US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

**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 ☐

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

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

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01 SEP 2022 23:59

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US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

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

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

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

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[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

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US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

**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 ☐

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

**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 ☐



**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

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

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[Patient Cloud Close Date & Time](#)

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22 SEP 2022 23:59

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US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

**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°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 ☐

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

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

25 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

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US3162037

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

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="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"/>

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	02 OCT 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	06 OCT 2022 23:59
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US3162037

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:27:33

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		27 FEB 2021 20:04:45

US3162037

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:35:18

Generated On: 09 Jun 2021 15:27:33

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 23 OCT 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3162037

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:35:18

Generated On: 09 Jun 2021 15:27:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3162037

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:34:21

Generated On: 09 Jun 2021 15:27:33

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 25 NOV 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3162037

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:34:21

Generated On: 09 Jun 2021 15:27:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162037

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:34:21

Generated On: 09 Jun 2021 15:27:33

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 23 DEC 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3162037

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:34:21

Generated On: 09 Jun 2021 15:27:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162037

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 01:34:21

Generated On: 09 Jun 2021 15:27:33

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3162037

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 01:34:21

Generated On: 09 Jun 2021 15:27:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162037

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 24 Apr 2021 22:50:42

Generated On: 09 Jun 2021 15:27:33

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

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

Folder OID	VISIT4
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US3162037

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 24 Apr 2021 22:50:42

Generated On: 09 Jun 2021 15:27:33

Were vital signs assessed? Yes ☐  
No ☒

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

Time of assessment (00:00-23:59) \_\_\_\_\_

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

Respiratory Rate units \_\_\_\_\_

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_



US3162037

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Apr 2021 22:50:42

Generated On: 09 Jun 2021 15:27:33

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.*

US3162037

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Apr 2021 22:50:42

Generated On: 09 Jun 2021 15:27:33

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

Collection date (dd MMM yyyy)	25 FEB 2021
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Collection time (00:00-23:59)	09:50 (24 HR)
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Collection date and time (derived)	25 FEB 2021 09:50
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US3162037

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 22:50:42

Generated On: 09 Jun 2021 15:27:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162037

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 24 Apr 2021 22:50:13

Generated On: 09 Jun 2021 15:27:33

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 26 MAR 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3162037

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 22:50:13

Generated On: 09 Jun 2021 15:27:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3162037**

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

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:27:33**

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*

**US3162037**

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

**Form: Continuing**

**Generated On: 09 Jun 2021 15:27:33**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**US3162037**

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

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 15:27:33**

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"/>



**US3162037**

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

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

**Generated On: 09 Jun 2021 15:27:33**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

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US3162037

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

Form: Visit Date

Data signed: (b) (4) 24 Apr 2021 22:50:12

Generated On: 09 Jun 2021 15:27:33

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

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

Folder OID	UNBLND_DECIDE
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US3162037

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

Form: Unblinding

Data signed: (b) (4) 24 Apr 2021 22:50:12

Generated On: 09 Jun 2021 15:27:33

Date of updated informed consent ( <i>dd MMM yyyy</i> )	25 FEB 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding ( <i>dd MMM yyyy</i> )	25 FEB 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3162037

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 24 Apr 2021 22:50:12

Generated On: 09 Jun 2021 15:27:33

Height	69 in
Weight	177.1 lb
BMI (xxx.x)	26.20778

US3162037

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 24 Apr 2021 22:50:12

Generated On: 09 Jun 2021 15:27:33

Height	69 in
Weight	177.1 lb
BMI (xxx.x)	26.20778
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 FEB 2021
Time of assessment (00:00-23:59)	11:24 (24 HR)
Vital Signs Date and Time (derived)	25 FEB 2021 11:24
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify _____	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	54 mmHg
Diastolic Blood Pressure units	MMHG

US3162037

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 24 Apr 2021 22:50:12

Generated On: 09 Jun 2021 15:27:33

Height	69 in
Weight	177.1 lb
BMI (xxx.x)	26.20778
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 FEB 2021
Time of assessment (00:00-23:59)	12:40 (24 HR)
Vital Signs Date and Time (derived)	25 FEB 2021 12:40
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify _____	
Pulse (xxx)	50 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	57 mmHg
Diastolic Blood Pressure units	MMHG

US3162037

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

Form: Physical Examination

Data signed: (b) (4) 24 Apr 2021 22:50:12

Generated On: 09 Jun 2021 15:27:33

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.*

US3162037

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

Form: Exposure

Data signed: (b) (4) 24 Apr 2021 22:50:12

Generated On: 09 Jun 2021 15:27:33

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 25 FEB 2021

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

Treatment Date and Time (derived) 25 FEB 2021 12:05

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

What was the frequency of the study treatment dosing? ONCE

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



US3162037

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Apr 2021 22:50:12

Generated On: 09 Jun 2021 15:27:33

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

Collection date (dd MMM yyyy)	25 FEB 2021
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Collection time (00:00-23:59)	09:50 (24 HR)
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Collection date and time (derived)	25 FEB 2021 09:50
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US3162037

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 24 Apr 2021 22:50:12

Generated On: 09 Jun 2021 15:27:33

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

Collection date (dd MMM yyyy)	25 FEB 2021
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Collection time (00:00 - 23:59)	09:47
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Collection Date and Time (derived)	25 FEB 2021 09:47
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US3162037

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

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 22:50:12

Generated On: 09 Jun 2021 15:27:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162037

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 24 Apr 2021 22:50:42

Generated On: 09 Jun 2021 15:27:33

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 4 MAR 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3162037

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 22:50:13

Generated On: 09 Jun 2021 15:27:33

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

US3162037

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 24 Apr 2021 22:50:12

Generated On: 09 Jun 2021 15:27:33

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

Visit date (dd MMM yyyy)	26 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	OLD29
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US3162037

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 24 Apr 2021 22:50:12

Generated On: 09 Jun 2021 15:27:33

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)	26 MAR 2021
Time of assessment (00:00-23:59)	12:18 (24 HR)
Vital Signs Date and Time (derived)	26 MAR 2021 12:18
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	55 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

US3162037

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 24 Apr 2021 22:50:12

Generated On: 09 Jun 2021 15:27:33

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)	26 MAR 2021
Time of assessment (00:00-23:59)	13:36 (24 HR)
Vital Signs Date and Time (derived)	26 MAR 2021 13:36
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	55 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	100 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	60 mmHg
Diastolic Blood Pressure units	MMHG



US3162037

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Apr 2021 22:50:12

Generated On: 09 Jun 2021 15:27:33

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.*

US3162037

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 24 Apr 2021 22:50:12

Generated On: 09 Jun 2021 15:27:33

Was study treatment given? Yes ☒  
No ☐

If No, reason not given

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

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

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

What was the treatment date? (dd MMM yyyy) 26 MAR 2021

What was the treatment time? (00:00-23:59) 13:01 (24 HR)

Treatment Date and Time (derived) 26 MAR 2021 13:01

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

US3162037

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 22:50:12

Generated On: 09 Jun 2021 15:27:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162037

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 24 Apr 2021 22:50:13

Generated On: 09 Jun 2021 15:27:33

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*

US3162037

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 22:50:13

Generated On: 09 Jun 2021 15:27:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162037

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 03 May 2021 18:47:15

Generated On: 09 Jun 2021 15:27:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3162037

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 03 May 2021 18:47:15

Generated On: 09 Jun 2021 15:27:33

Were vital signs assessed? Yes ☐  
No ☒

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

Time of assessment (00:00-23:59) \_\_\_\_\_

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

Respiratory Rate units \_\_\_\_\_

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3162037

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 03 May 2021 18:47:15

Generated On: 09 Jun 2021 15:27:33

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.*



US3162037

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 03 May 2021 18:47:15

Generated On: 09 Jun 2021 15:27:33

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	30 APR 2021
Collection time (00:00-23:59)	12:35 (24 HR)
Collection date and time (derived)	30 APR 2021 12:35

US3162037

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 13 Feb 2021 01:34:20

Generated On: 09 Jun 2021 15:27:33

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3162037

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 24 Apr 2021 22:50:12

Generated On: 09 Jun 2021 15:27:33

AEID	
Adverse event	HEADACHE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" 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)	07 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	07 AUG 2020
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	

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 24 Apr 2021 22:50:12

Generated On: 09 Jun 2021 15:27:33

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

US3162037

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 24 Apr 2021 22:50:12

Generated On: 09 Jun 2021 15:27:33

AEID	
Adverse event	LEFT SHOULDER PAIN
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" 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)	23 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	15 JAN 2021
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	

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 24 Apr 2021 22:50:12

Generated On: 09 Jun 2021 15:27:33

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

US3162037

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 24 Apr 2021 22:50:12

Generated On: 09 Jun 2021 15:27:33

AEID	USA-US074-2021-MRNA-1273-P30 1000012
Adverse event	DEVELOPING AVASCULAR NECROSIS OF LEFT 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)	08 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	8 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	8 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	9 FEB 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 24 Apr 2021 22:50:12

Generated On: 09 Jun 2021 15:27:33

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
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	



US3162037

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 24 Apr 2021 22:50:12

Generated On: 09 Jun 2021 15:27:33

SUBJECT HAD ONSET OF LEFT HIP PAIN IN MAY2020. MRI ON 13NOV2020 SUGGESTED "DEVELOPING AVASCULAR NECROSIS" OF LEFT HIP. XRAY OF LEFT HIP ON 08JAN2021 HAD SHOWN MODERATE TO ADVANCED OSTEOARTHRITIS OF THE LEFT HIP. SUBJECT WAS ADMITTED TO HOSPITAL FOR PLANNED SURGERY ON 8FEB2021, HAD TOTAL LEFT HIP ARTHROPLASTY THAT DAY, DISCHARGED TO HOME ON 9FEB2021. RELEVANT LAB RESULTS FROM 09FEB21 INCLUDE: WBC 16,900 PER MICROLITER (NORMAL 4500-10,700 PER MICROLITER, HEMOGLOBIN 9.6 GRAMS PER DECILITER (NORMAL 12.0 TO 15.0 GRAMS PER DECILITER), HEMATOCRIT 29% (NORMAL 36 TO 45%)

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

US3162037

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 24 Apr 2021 22:50:12

Generated On: 09 Jun 2021 15:27:33

AEID	
Adverse event	PAIN FROM LEFT HIP REPLACEMENT
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)	8 FEB 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 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"/>

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 24 Apr 2021 22:50:12

Generated On: 09 Jun 2021 15:27:33

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/>
	Dose Delayed <input type="radio"/>
	Investigational Product <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 checked="" 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)	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 24 Apr 2021 22:50:12

Generated On: 09 Jun 2021 15:27:33

AEID

Adverse event

WORSENING OF LEFT HIP PAIN

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)

01 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

08 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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US3162037

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 24 Apr 2021 22:50:12

Generated On: 09 Jun 2021 15:27:33

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

US3162037

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 24 Apr 2021 22:50:12

Generated On: 09 Jun 2021 15:27:33

AEID

Adverse event

OSTEOARTHRITIS OF LEFT HIP

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)

8 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

8 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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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 24 Apr 2021 22:50:12

Generated On: 09 Jun 2021 15:27:33

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
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)	_____

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 13 Feb 2021 01:34:21

Generated On: 09 Jun 2021 15:27:33

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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.

---



US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 03 May 2021 18:47:15

Generated On: 09 Jun 2021 15:27:33

Name of Medication ALENDRONATE

Prophylaxis Yes ☐  
No ☒

Indication OSTEOGENIA

Dose per administration 70

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 03 May 2021 18:47:15

Generated On: 09 Jun 2021 15:27:33

	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 MAR 2018	
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 checked="" type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 03 May 2021 18:47:15

Generated On: 09 Jun 2021 15:27:33

Name of Medication FLUOXETINE

Prophylaxis Yes ☐  
No ☒

Indication DEPRESSION

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 03 May 2021 18:47:15

Generated On: 09 Jun 2021 15:27:33

	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 MAR 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 03 May 2021 18:47:15

Generated On: 09 Jun 2021 15:27:33

Name of Medication METOPROLOL TARTRATE

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 03 May 2021 18:47:15

Generated On: 09 Jun 2021 15:27:33

	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 JUN 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 03 May 2021 18:47:15

Generated On: 09 Jun 2021 15:27:33

Name of Medication DRONEDARONE

Prophylaxis Yes ☐  
No ☒

Indication ATRIAL FIBRILLATION

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 03 May 2021 18:47:15

Generated On: 09 Jun 2021 15:27:33

	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 MAY 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)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 03 May 2021 18:47:15

Generated On: 09 Jun 2021 15:27:33

Name of Medication HYDROCODONE/ACETAMINOP  
HEN

Prophylaxis Yes ☐  
No ☒

Indication OSTEOARTHRITIS LOWER  
BACK

Dose per administration 5/325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 03 May 2021 18:47:15

Generated On: 09 Jun 2021 15:27:33

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN MAR 2018	
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)

Data signed: (b) (4) 03 May 2021 18:47:15

Generated On: 09 Jun 2021 15:27:33

Name of Medication PRAMIPEXOLE

Prophylaxis Yes ☐  
No ☒

Indication RESTLESS LEG SYNDROME,  
BILATERAL

Dose per administration .25

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 03 May 2021 18:47:15

Generated On: 09 Jun 2021 15:27:33

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN MAY 2018	
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 (7)

Data signed: (b) (4) 03 May 2021 18:47:15

Generated On: 09 Jun 2021 15:27:33

Name of Medication PRAVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 80

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 03 May 2021 18:47:15

Generated On: 09 Jun 2021 15:27:33

	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 MAR 2018	
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 (8)

Data signed: (b) (4) 03 May 2021 18:47:15

Generated On: 09 Jun 2021 15:27:33

Name of Medication RIVAROXABAN

Prophylaxis Yes ☐  
No ☒

Indication ATRIAL FIBRILLATION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 03 May 2021 18:47:15

Generated On: 09 Jun 2021 15:27:33

	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 MAR 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 03 May 2021 18:47:15

Generated On: 09 Jun 2021 15:27:33

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication OSTEOARTHRITIS LOWER  
BACK (LEFT AND RIGHT HIP  
PAIN)

Dose per administration 800

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 03 May 2021 18:47:15

Generated On: 09 Jun 2021 15:27:33

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	18 DEC 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"/>

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 03 May 2021 18:47:15

Generated On: 09 Jun 2021 15:27:33

Name of Medication NAPROXEN

Prophylaxis Yes ☐  
No ☒

Indication HEADACHE

Dose per administration 660

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 03 May 2021 18:47:15

Generated On: 09 Jun 2021 15:27:33

	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)	07 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		07 AUG 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input 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 (11)

Data signed: (b) (4) 03 May 2021 18:47:15

Generated On: 09 Jun 2021 15:27:33

Name of Medication CELECOXIB

Prophylaxis Yes ☐  
No ☒

Indication LEFT AND RIGHT HIP PAIN

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 03 May 2021 18:47:15

Generated On: 09 Jun 2021 15:27:33

	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 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	7 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 03 May 2021 18:47:15

Generated On: 09 Jun 2021 15:27:33

Name of Medication	KENALOG
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	OSTEOARTHRITIS (LOWER BACK)
Dose per administration	40
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 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 03 May 2021 18:47:15

Generated On: 09 Jun 2021 15:27:33

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



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 03 May 2021 18:47:15

Generated On: 09 Jun 2021 15:27:33

Name of Medication NAPROXEN

Prophylaxis Yes ☐  
No ☒

Indication LEFT SHOULDER PAIN

Dose per administration 660

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 03 May 2021 18:47:15

Generated On: 09 Jun 2021 15:27:33

	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)	23 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		13 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 (14)

Data signed: (b) (4) 03 May 2021 18:47:15

Generated On: 09 Jun 2021 15:27:33

Name of Medication KENALOG

Prophylaxis Yes ☐  
No ☒

Indication RIGHT HIP PAIN

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 03 May 2021 18:47:15

Generated On: 09 Jun 2021 15:27:33

	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 checked="" type="radio"/>
If route of administration is Other, specify	INTRAARTICULAR	
Start date (dd MMM yyyy)	16 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	16 SEP 2020	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 03 May 2021 18:47:15

Generated On: 09 Jun 2021 15:27:33

Name of Medication KENALOG

Prophylaxis Yes ☐  
No ☒

Indication WORSENING OF LEFT HIP PAIN

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 03 May 2021 18:47:15

Generated On: 09 Jun 2021 15:27:33

	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 checked="" type="radio"/>
If route of administration is Other, specify	INTRAARTICULAR	
Start date (dd MMM yyyy)	22 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	22 SEP 2020	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 03 May 2021 18:47:15

Generated On: 09 Jun 2021 15:27:33

Name of Medication CELECOXIB

Prophylaxis Yes ☐  
No ☒

Indication PAIN FROM LEFT HIP  
REPLACEMENT

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 03 May 2021 18:47:15

Generated On: 09 Jun 2021 15:27:33

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		08 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 03 May 2021 18:47:15

Generated On: 09 Jun 2021 15:27:33

Name of Medication OXYCODONE/ACETAMINOPHE  
N

Prophylaxis Yes ☐  
No ☒

Indication PAIN FROM LEFT HIP  
REPLACEMENT

Dose per administration 5/325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 03 May 2021 18:47:15

Generated On: 09 Jun 2021 15:27:33

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	08 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		19 MAR 2021
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 (18)

Data signed: (b) (4) 03 May 2021 18:47:15

Generated On: 09 Jun 2021 15:27:33

Name of Medication HYDROCODONE/ACETAMINOP  
HEN

Prophylaxis Yes ☐  
No ☒

Indication RIGHT HIP PAIN AND  
WORSENING OF LEFT HIP PAIN

Dose per administration 5/325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 03 May 2021 18:47:15

Generated On: 09 Jun 2021 15:27:33

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	20 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
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 (19)

Data signed: (b) (4) 03 May 2021 18:47:15

Generated On: 09 Jun 2021 15:27:33

Name of Medication TYLENOL WITH CODEINE

Prophylaxis Yes ☐  
No ☒

Indication LEFT AND RIGHT HIP PAIN

Dose per administration 30/300

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 03 May 2021 18:47:15

Generated On: 09 Jun 2021 15:27:33

	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)	13 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
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 (20)

Data signed: (b) (4) 03 May 2021 18:47:15

Generated On: 09 Jun 2021 15:27:33

Name of Medication VERSED

Prophylaxis Yes ☐  
No ☒

Indication SEDATION FOR LEFT TOTAL  
HIP ARTHROPLASTY

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 03 May 2021 18:47:15

Generated On: 09 Jun 2021 15:27:33

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	08 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		08 FEB 2021
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 (21)

Data signed: (b) (4) 03 May 2021 18:47:15

Generated On: 09 Jun 2021 15:27:33

Name of Medication CLINDAMYCIN

Prophylaxis Yes ☒  
No ☐

Indication PREVENT INFECTION FROM  
LEFT TOTAL HIP  
ARTHROPLASTY

Dose per administration 900

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 03 May 2021 18:47:15

Generated On: 09 Jun 2021 15:27:33

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	08 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		08 FEB 2021
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 (22)

Data signed: (b) (4) 03 May 2021 18:47:15

Generated On: 09 Jun 2021 15:27:33

Name of Medication PROPOFOL

Prophylaxis Yes ☐  
No ☒

Indication GENERAL ANESTHESIA FOR  
LEFT TOTAL HIP  
ARTHROPLASTY

Dose per administration 150

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 03 May 2021 18:47:15

Generated On: 09 Jun 2021 15:27:33

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	08 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		08 FEB 2021
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 (23)

Data signed: (b) (4) 03 May 2021 18:47:15

Generated On: 09 Jun 2021 15:27:33

Name of Medication FENTANYL

Prophylaxis Yes ☐  
No ☒

Indication GENERAL ANESTHESIA FOR  
LEFT TOTAL HIP  
ARTHROPLASTY

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 03 May 2021 18:47:15

Generated On: 09 Jun 2021 15:27:33

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	08 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		08 FEB 2021
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 (24)

Data signed: (b) (4) 03 May 2021 18:47:15

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Name of Medication KETAMINE

Prophylaxis Yes ☐  
No ☒

Indication GENERAL ANESTHESIA FOR  
LEFT TOTAL HIP  
ARTHROPLASTY

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 03 May 2021 18:47:15

Generated On: 09 Jun 2021 15:27:33

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	08 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		08 FEB 2021
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 (25)

Data signed: (b) (4) 03 May 2021 18:47:15

Generated On: 09 Jun 2021 15:27:33

Name of Medication LIDOCAINE

Prophylaxis Yes ☐  
No ☒

Indication REGIONAL ANESTHESIA FOR  
LEFT TOTAL HIP  
ARTHROPLASTY

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 03 May 2021 18:47:15

Generated On: 09 Jun 2021 15:27:33

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	08 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		08 FEB 2021
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 (26)

Data signed: (b) (4) 03 May 2021 18:47:15

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Name of Medication ZOFRAN

Prophylaxis Yes ☒  
No ☐

Indication PREVENTION OF  
NAUSEA/VOMITING DURING  
LEFT TOTAL HIP  
ARTHROPLASTY

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 03 May 2021 18:47:15

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	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	08 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	08 FEB 2021	
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 (27)

Data signed: (b) (4) 03 May 2021 18:47:15

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Name of Medication DECADRON

Prophylaxis Yes ☒  
No ☐

Indication PREVENT INFLAMMATION  
FROM LEFT TOTAL HIP  
ARTHROPLASTY

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 03 May 2021 18:47:15

Generated On: 09 Jun 2021 15:27:33

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	08 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		08 FEB 2021
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 (28)

Data signed: (b) (4) 03 May 2021 18:47:15

Generated On: 09 Jun 2021 15:27:33

Name of Medication EPHEDRINE

Prophylaxis Yes ☒  
No ☐

Indication PREVENTION OF  
BRONCHOSPASM DURING LEFT  
TOTAL HIP ARTHROPLASTY

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 03 May 2021 18:47:15

Generated On: 09 Jun 2021 15:27:33

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	08 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		08 FEB 2021
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 (29)

Data signed: (b) (4) 03 May 2021 18:47:15

Generated On: 09 Jun 2021 15:27:33

Name of Medication PHENYLEPHRINE 0.75%

Prophylaxis Yes ☒  
No ☐

Indication PREVENT INTRAOPERATIVE  
HYPOTENSION DURING LEFT  
TOTAL HIP ARTHROPLASTY

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 03 May 2021 18:47:15

Generated On: 09 Jun 2021 15:27:33

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	08 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		08 FEB 2021
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"/>

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 03 May 2021 18:47:15

Generated On: 09 Jun 2021 15:27:33

Name of Medication BUPIVACAINE

Prophylaxis Yes ☐  
No ☒

Indication LOCAL ANESTHESIA FOR LEFT  
TOTAL HIP ARTHROPLASTY

Dose per administration 1.6

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 03 May 2021 18:47:15

Generated On: 09 Jun 2021 15:27:33

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	08 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		08 FEB 2021
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"/>

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 03 May 2021 18:47:15

Generated On: 09 Jun 2021 15:27:33

Name of Medication LACTATED RINGERS

Prophylaxis Yes ☐  
No ☒

Indication INTRAOPERATIVE HYDRATION  
FOR LEFT TOTAL HIP  
ARTHROPLASTY

Dose per administration 1300

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

If dose unit is Other, specify CC

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 03 May 2021 18:47:15

Generated On: 09 Jun 2021 15:27:33

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	08 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		08 FEB 2021
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"/>

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 03 May 2021 18:47:15

Generated On: 09 Jun 2021 15:27:33

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication PAIN FROM LEFT HIP  
REPLACEMENT

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 03 May 2021 18:47:15

Generated On: 09 Jun 2021 15:27:33

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	14 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"/>



US3162037

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 08 Apr 2021 21:29:23

Generated On: 09 Jun 2021 15:27:33

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3162037

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 24 Apr 2021 22:50:12

Generated On: 09 Jun 2021 15:27:33

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
8 FEB 2021	LEFT HIP ARTHROPLASTY	Adverse Event	
13 NOV 2020	MRI OF THE LEFT HIP WITHOUT CONTRAST	Medical History	
08 JAN 2021	XRAY OF PELVIS AND BILATERAL HIPS	Adverse Event	

US3162037

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:27:33

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

US3162037

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:27:33

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 ☐

US3162037

Folder: SAE USA-US074-2021-MRNA-1273-P301000012

Form: Safety Report Form

Data signed: (b) (4) 24 Apr 2021 22:50:13

Generated On: 09 Jun 2021 15:27:33

SAEID	USA-US074-2021-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JUDITH
Investigator's Last Name	KIRSTEIN
Site Address: Street	264 N HIGHLAND SPRINGS AVE, SUITE 4
Site Address: City	BANNING
Site Address: State	CA
Site Address: Postal Code	92220
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3162037

Folder: SAE USA-US074-2021-MRNA-1273-P301000012

Form: Safety Report Form (1)

Data signed: (b) (4) 24 Apr 2021 22:50:13

Generated On: 09 Jun 2021 15:27:33

SAEID	USA-US074-2021-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JUDITH
Investigator's Last Name	KIRSTEIN
Site Address: Street	264 N HIGHLAND SPRINGS AVE, SUITE 4
Site Address: City	BANNING
Site Address: State	CA
Site Address: Postal Code	92220
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	16/FEB/2021 23:03
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

US3162037

Folder: SAE USA-US074-2021-MRNA-1273-P301000012

Form: Safety Report Form (2)

Data signed: (b) (4) 24 Apr 2021 22:50:13

Generated On: 09 Jun 2021 15:27:33

SAEID	USA-US074-2021-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JUDITH
Investigator's Last Name	KIRSTEIN
Site Address: Street	264 N HIGHLAND SPRINGS AVE, SUITE 4
Site Address: City	BANNING
Site Address: State	CA
Site Address: Postal Code	92220
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	22/FEB/2021 12:11
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3162037

Folder: SAE USA-US074-2021-MRNA-1273-P301000012

Form: Safety Report Form (3)

Data signed: (b) (4) 24 Apr 2021 22:50:13

Generated On: 09 Jun 2021 15:27:33

SAEID	USA-US074-2021-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JUDITH
Investigator's Last Name	KIRSTEIN
Site Address: Street	264 N HIGHLAND SPRINGS AVE, SUITE 4
Site Address: City	BANNING
Site Address: State	CA
Site Address: Postal Code	92220
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	14/APR/2021 11:06
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



US3162037

Folder: SAE USA-US074-2021-MRNA-1273-P301000012

Form: Safety Report Form (4)

Data signed: (b) (4) 24 Apr 2021 22:50:13

Generated On: 09 Jun 2021 15:27:33

SAEID	USA-US074-2021-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JUDITH
Investigator's Last Name	KIRSTEIN
Site Address: Street	264 N HIGHLAND SPRINGS AVE, SUITE 4
Site Address: City	BANNING
Site Address: State	CA
Site Address: Postal Code	92220
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	20/APR/2021 09:28
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3162037 (Prod: Advanced Clinical Research - Rancho Paseo - ERN - PPDS)

**US3162037**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 15:27:33**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'US3162037'	RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 20:04:22

US3162037

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:27:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 02:40:02

US3162037

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '31 JUL 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 20:04:23

US3162037

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:27:33

[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 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'Clinic (Clinic)'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 02:40:02

**US3162037**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:27:33**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered 'SCRN'	System	01 Aug 2020 02:40:02

US3162037

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:27:33

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered (b) (6) 1952'	RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 20:04:24



US3162037

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:27:33

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '68'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 02:40:17

**US3162037**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:27:33**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered 'YEARS'	System	01 Aug 2020 02:40:17

**US3162037**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:27:33**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered '68'	System	31 Jul 2020 22:06:59

**US3162037**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:27:33**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'Female (F)'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 02:40:17

US3162037

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:27:33

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 02:40:17

US3162037

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:27:33

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'I'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 02:40:17

**US3162037**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:27:33**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 02:40:17

**US3162037**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:27:33**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 02:40:17



**US3162037**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:27:33**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 02:40:17

US3162037

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:27:33

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 02:40:17

**US3162037**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:27:33**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 02:40:17

US3162037

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:27:33

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 02:40:17

**US3162037**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:27:33**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 02:40:17

**US3162037**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:27:33**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 02:40:17

US3162037

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:27:33

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '31 Jul 2020'	Jared Bradshaw (b) (4) (b) (4)	31 Jul 2020 22:06:59

US3162037

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered 'Jul 2020'	System	31 Jul 2020 22:06:59



**US3162037**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered '2020'	System	31 Jul 2020 22:06:59

US3162037

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:27:33

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'Amendment 1 (1)'	Jared Bradshaw (b) (4) (b) (4)	31 Jul 2020 22:06:59

US3162037

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	31 Jul 2020 22:06:59

US3162037

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:27:33

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	31 Jul 2020 22:06:59

US3162037

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:27:33

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	31 Jul 2020 22:06:59

US3162037

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:27:33

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	31 Jul 2020 22:06:59

US3162037

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:27:33

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 20:04:23

US3162037

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:27:33

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered 'I'	System	31 Jul 2020 22:07:05



US3162037

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	31 Jul 2020 22:07:05

US3162037

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:27:33

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 02:40:25

US3162037

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:27:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
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: Penicillin allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 02:41:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 02:41:10
Data point term sent to Coder	System	01 Aug 2020 02:41:00
User entered 'penicillin allergy'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 02:40:49

**US3162037**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'un UNK 1990'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 02:40:49

**US3162037**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:27:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 02:40:49

**US3162037**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:27:33**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 02:40:49

US3162037

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 02:40:49

**US3162037**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:27:33**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 02:40:49



**US3162037**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered 'Jan 1990'	System	01 Aug 2020 02:40:49

**US3162037**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered '1990'	System	01 Aug 2020 02:40:49

**US3162037**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered empty.	System	01 Aug 2020 02:40:49

**US3162037**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered empty.	System	01 Aug 2020 02:40:49

US3162037

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:27:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
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: Sulfonamide allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Sep 2020 05:55:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Sep 2020 05:55:40
Data point term sent to Coder	System	15 Sep 2020 05:54:43
Coding entries removed.	Judith Kirstein (b) (4) (b) (4)	15 Sep 2020 05:54:04
User entered 'SULFA ALLERGY' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	15 Sep 2020 05:54:04
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: Sulfonamide allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 13:56:23
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 13:56:23
Data point term sent to Coder	System	01 Aug 2020 02:42:01
User entered 'sulfa allergy'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 02:41:06

US3162037

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'un UNK 1990'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 02:41:06

**US3162037**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:27:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 02:41:06

US3162037

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:27:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Aug 2020 02:41:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Aug 2020 02:41:18
User entered 'Yes (Y)' reason for change: New Information	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 02:41:18
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Aug 2020 02:41:06
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 02:41:06



US3162037

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 02:41:06

US3162037

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:27:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 02:41:06

**US3162037**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered 'Jan 1990'	System	01 Aug 2020 02:41:06

**US3162037**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered '1990'	System	01 Aug 2020 02:41:06

**US3162037**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered empty.	System	01 Aug 2020 02:41:06

**US3162037**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered empty.	System	01 Aug 2020 02:41:06

US3162037

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:27:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Menopause, LLT: Natural menopause - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 04:13:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 04:13:09
Data point term sent to Coder	System	01 Aug 2020 04:12:45
User entered 'natural menopause'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 04:12:32

**US3162037**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'un UNK 2005'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 04:12:32



**US3162037**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:27:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 04:12:32

**US3162037**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:27:33**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 04:12:32

US3162037

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 04:12:32

**US3162037**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:27:33**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 04:12:32

**US3162037**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered 'Jan 2005'	System	01 Aug 2020 04:12:32

**US3162037**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered '2005'	System	01 Aug 2020 04:12:32

**US3162037**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered empty.	System	01 Aug 2020 04:12:32

**US3162037**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered empty.	System	01 Aug 2020 04:12:32



US3162037

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:27:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergy to antibiotic - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 02:43:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 02:43:10
Data point term sent to Coder	System	01 Aug 2020 02:42:01
User entered 'erythromycin allergy'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 02:41:41

US3162037

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'un UNK 1990'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 02:41:41

**US3162037**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:27:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 02:41:41

US3162037

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:27:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 02:41:41

**US3162037**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:27:33**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 02:41:41

US3162037

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:27:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 02:41:41

**US3162037**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered 'Jan 1990'	System	01 Aug 2020 02:41:41

**US3162037**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered '1990'	System	01 Aug 2020 02:41:41



**US3162037**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered empty.	System	01 Aug 2020 02:41:41

**US3162037**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered empty.	System	01 Aug 2020 02:41:41

US3162037

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:27:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergy to antibiotic - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 10:53:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 10:53:49
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: Allergic reaction to antibiotics - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 14:03:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 14:03:43
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 02:43:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 02:43:10
Data point term sent to Coder	System	01 Aug 2020 02:42:01
User entered 'tetracycline allergy'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 02:41:57

**US3162037**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'un UNK 1990'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 02:41:57

**US3162037**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:27:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 02:41:57

US3162037

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:27:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 02:41:57

US3162037

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 02:41:57

**US3162037**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:27:33**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 02:41:57



**US3162037**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered 'Jan 1990'	System	01 Aug 2020 02:41:57

**US3162037**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered '1990'	System	01 Aug 2020 02:41:57

**US3162037**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered empty.	System	01 Aug 2020 02:41:57

**US3162037**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered empty.	System	01 Aug 2020 02:41:57

US3162037

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:27:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Metabolic bone disorders, PT: Osteopenia, LLT: Osteopenia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 02:43:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 02:43:10
Data point term sent to Coder	System	01 Aug 2020 02:43:01
User entered 'osteopenia'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 02:42:16

US3162037

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'un Mar 2018'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 02:42:16

US3162037

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:27:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 02:42:16

US3162037

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:27:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 02:42:16



US3162037

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 02:42:16

US3162037

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:27:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 02:42:16

**US3162037**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered 'Mar 2018'	System	01 Aug 2020 02:42:16

**US3162037**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered '2018'	System	01 Aug 2020 02:42:16

**US3162037**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered empty.	System	01 Aug 2020 02:42:16

**US3162037**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered empty.	System	01 Aug 2020 02:42:16

US3162037

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:27:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 02:43:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 02:43:10
Data point term sent to Coder	System	01 Aug 2020 02:43:01
User entered 'depression'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 02:42:32

**US3162037**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'un UNK 1999'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 02:42:32



**US3162037**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:27:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 02:42:32

US3162037

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:27:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 02:42:32

**US3162037**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:27:33**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 02:42:32

US3162037

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:27:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 02:42:32

**US3162037**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered 'Jan 1999'	System	01 Aug 2020 02:42:32

**US3162037**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered '1999'	System	01 Aug 2020 02:42:32

**US3162037**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered empty.	System	01 Aug 2020 02:42:32

**US3162037**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered empty.	System	01 Aug 2020 02:42:32



US3162037

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:27:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 02:43:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 02:43:10
Data point term sent to Coder	System	01 Aug 2020 02:43:01
User entered 'hypertension'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 02:42:49

US3162037

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'un Jun 2018'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 02:42:49

US3162037

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:27:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 02:42:49

**US3162037**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:27:33**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 02:42:49

US3162037

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 02:42:49

**US3162037**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:27:33**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 02:42:49

**US3162037**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered 'Jun 2018'	System	01 Aug 2020 02:42:49

**US3162037**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered '2018'	System	01 Aug 2020 02:42:49



**US3162037**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered empty.	System	01 Aug 2020 02:42:49

**US3162037**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered empty.	System	01 Aug 2020 02:42:49

US3162037

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:27:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Sep 2020 06:05:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Sep 2020 06:05:41
Data point term sent to Coder	System	15 Sep 2020 06:04:44
Coding entries removed.	Judith Kirstein (b) (4) (b) (4)	15 Sep 2020 06:04:06
User entered 'INTERMITTENT ATRIAL FIBRILLATION' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	15 Sep 2020 06:04:06
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 02:45:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 02:45:11
Data point term sent to Coder	System	01 Aug 2020 02:44:02
User entered 'atrial fibrillation'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 02:43:05

**US3162037**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'un Mar 2018'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 02:43:05

**US3162037**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:27:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 02:43:05

**US3162037**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:27:33**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 02:43:05

US3162037

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 02:43:05

US3162037

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:27:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 02:43:05



**US3162037**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered 'Mar 2018'	System	01 Aug 2020 02:43:05

**US3162037**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered '2018'	System	01 Aug 2020 02:43:05

**US3162037**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered empty.	System	01 Aug 2020 02:43:05

**US3162037**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered empty.	System	01 Aug 2020 02:43:05

US3162037

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:27:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc degeneration, LLT: Degenerative disc disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 08:03:05
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 08:03:05
Data point term sent to Coder	System	01 Aug 2020 03:09:28
User entered 'degenerative disc disease C5, C6, C7'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:08:59

US3162037

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:27:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'un Mar 2018'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:08:59

**US3162037**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:27:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:08:59

**US3162037**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:27:33**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:08:59



US3162037

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:08:59

**US3162037**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:27:33**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:08:59

**US3162037**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered 'Mar 2018'	System	01 Aug 2020 03:08:59

**US3162037**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered '2018'	System	01 Aug 2020 03:08:59

**US3162037**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered empty.	System	01 Aug 2020 03:08:59

**US3162037**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered empty.	System	01 Aug 2020 03:08:59

US3162037

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:27:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Spinal osteoarthritis, LLT: Osteoarthritis of lumbar spine - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 17:02:10
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 17:02:10
Data point term sent to Coder	System	01 Aug 2020 03:10:28
User entered 'osteoarthritis lower back'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:09:43

US3162037

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'un UNK 2015'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:09:43



US3162037

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:27:33

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:09:43

**US3162037**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 15:27:33**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:09:43

**US3162037**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 15:27:33**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:09:43

US3162037

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:27:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:09:43

**US3162037**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered 'Jan 2015'	System	01 Aug 2020 03:09:43

**US3162037**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered '2015'	System	01 Aug 2020 03:09:43

**US3162037**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered empty.	System	01 Aug 2020 03:09:43

**US3162037**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered empty.	System	01 Aug 2020 03:09:43



US3162037

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:27:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Sensory abnormalities NEC, PT: Restless legs syndrome, LLT: Restless leg syndrome - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 23:37:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 23:37:46
User closed query 'Per DM CLR: Please specify the laterality of RESTLESS LEG SYNDROME. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 19:48:14
Query 'Per DM CLR: Please specify the laterality of RESTLESS LEG SYNDROME. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'LATERALITY ADDED PER QUERY' (Site from DM).	Judith Kirstein (b) (4) (b) (4)	15 Sep 2020 17:35:09
Data point term sent to Coder	System	15 Sep 2020 17:34:58
Coding entries removed.	Judith Kirstein (b) (4) (b) (4)	15 Sep 2020 17:34:53
User entered 'RESTLESS LEG SYNDROME, BILATERAL' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	15 Sep 2020 17:34:53
User opened query 'Per DM CLR: Please specify the laterality of RESTLESS LEG SYNDROME. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 07:21:39

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Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:27:33

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Sensory abnormalities NEC, PT: Restless legs syndrome, LLT: Restless leg syndrome - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 03:12:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 03:12:17
Data point term sent to Coder	System	01 Aug 2020 03:11:29
User entered 'restless leg syndrome'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:10:29

US3162037

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	01 Aug 2020 03:10:55
User entered 'un May 2018' reason for change: Data Entry Error	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:10:55
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	01 Aug 2020 03:10:29
User entered '00 May 2018' (non-conformant).	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:10:29

US3162037

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:27:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:10:29

US3162037

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:27:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:10:29

US3162037

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:10:29

US3162037

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:27:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:10:29

US3162037

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered 'May 2018'	System	01 Aug 2020 03:10:55
User entered empty.	System	01 Aug 2020 03:10:29



US3162037

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:27:33

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered '2018'	System	01 Aug 2020 03:10:55
User entered empty.	System	01 Aug 2020 03:10:29

**US3162037**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered empty.	System	01 Aug 2020 03:10:29

**US3162037**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered empty.	System	01 Aug 2020 03:10:29

US3162037

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:27:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Pain in hip - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 15:16:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 15:16:36
Data point term sent to Coder	System	31 Aug 2020 15:15:54
User entered 'Left hip pain'	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:15:35

US3162037

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:27:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'un May 2020'	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:15:35

US3162037

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:27:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:15:35

US3162037

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:27:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:15:35

**US3162037**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 15:27:33**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:15:35



**US3162037**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 15:27:33**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:15:35

**US3162037**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered 'May 2020'	System	31 Aug 2020 15:15:35

**US3162037**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered '2020'	System	31 Aug 2020 15:15:35

**US3162037**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered empty.	System	31 Aug 2020 15:15:35

**US3162037**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered empty.	System	31 Aug 2020 15:15:35

US3162037

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:27:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 03:13:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 03:13:17
Data point term sent to Coder	System	01 Aug 2020 03:12:30
User entered 'hyperlipidemia'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:11:48

US3162037

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'un Mar 2018'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:11:48

US3162037

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:27:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:11:48



US3162037

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:27:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:11:48

US3162037

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:11:48

**US3162037**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 15:27:33**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:11:48

**US3162037**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered 'Mar 2018'	System	01 Aug 2020 03:11:48

**US3162037**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered '2018'	System	01 Aug 2020 03:11:48

**US3162037**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered empty.	System	01 Aug 2020 03:11:48

**US3162037**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered empty.	System	01 Aug 2020 03:11:48

US3162037

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:27:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Appendicitis, LLT: Appendicitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 03:14:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 03:14:17
Data point term sent to Coder	System	01 Aug 2020 03:13:31
User entered 'appendicitis'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:13:01



US3162037

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'un UNK 1996'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:13:01

**US3162037**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 15:27:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:13:01

US3162037

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:27:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:13:01

US3162037

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'un UNK 1996'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:13:01

**US3162037**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 15:27:33**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:13:01

**US3162037**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered 'Jan 1996'	System	01 Aug 2020 03:13:01

**US3162037**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered '1996'	System	01 Aug 2020 03:13:01

**US3162037**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered 'Jan 1996'	System	01 Aug 2020 03:13:01



**US3162037**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered '1996'	System	01 Aug 2020 03:13:01

US3162037

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:27:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Abdominal hernias NEC, PT: Abdominal hernia, LLT: Ventral hernia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 17:11:03
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 17:11:03
Data point term sent to Coder	System	01 Aug 2020 03:15:33
User entered 'recurrent ventral hernia'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:14:41

US3162037

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'un UNK 2015'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:14:41

**US3162037**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 15:27:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:14:41

US3162037

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:27:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:14:41

US3162037

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'un UNK 2015'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:14:41

**US3162037**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 15:27:33**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:14:41

**US3162037**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered 'Jan 2015'	System	01 Aug 2020 03:14:41



**US3162037**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered '2015'	System	01 Aug 2020 03:14:41

**US3162037**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered 'Jan 2015'	System	01 Aug 2020 03:14:41

**US3162037**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered '2015'	System	01 Aug 2020 03:14:41

US3162037

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:27:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal stenosis and obstruction, HLT: Duodenal and small intestinal stenosis and obstruction, PT: Small intestinal obstruction, LLT: Small bowel obstruction - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 03:17:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 03:17:17
Data point term sent to Coder	System	01 Aug 2020 03:16:34
User entered 'small bowel obstruction'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:15:38

US3162037

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'un UNK 1997'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:15:38

**US3162037**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 15:27:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:15:38

US3162037

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:27:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:15:38

**US3162037**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 15:27:33**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'un UNK 1997'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:15:38



US3162037

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:27:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:15:38

**US3162037**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered 'Jan 1997'	System	01 Aug 2020 03:15:38

**US3162037**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered '1997'	System	01 Aug 2020 03:15:38

**US3162037**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered 'Jan 1997'	System	01 Aug 2020 03:15:38

**US3162037**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered '1997'	System	01 Aug 2020 03:15:38

US3162037

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:27:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User closed query 'Per DM CLR: Please specify the location of TINNITUS (Right, Left or Bilateral). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 19:48:48
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Inner ear and VIIIth cranial nerve disorders, HLT: Inner ear signs and symptoms, PT: Tinnitus, LLT: Tinnitus - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Sep 2020 17:36:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Sep 2020 17:36:52
Query 'Per DM CLR: Please specify the location of TINNITUS (Right, Left or Bilateral). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'UPDATED PER QUERY' (Site from DM).	Judith Kirstein (b) (4) (b) (4)	15 Sep 2020 17:36:09
Data point term sent to Coder	System	15 Sep 2020 17:35:59
Coding entries removed.	Judith Kirstein (b) (4) (b) (4)	15 Sep 2020 17:35:53
User entered 'BILATERAL TINNITUS' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	15 Sep 2020 17:35:53
User opened query 'Per DM CLR: Please specify the location of TINNITUS (Right, Left or Bilateral). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 07:22:08

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Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:27:33

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Inner ear and VIIIth cranial nerve disorders, HLT: Inner ear signs and symptoms, PT: Tinnitus, LLT: Tinnitus - version MedDRA\\23.0.	Coder Import (b) (4)	01 Aug 2020 03:18:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Aug 2020 03:18:17
Data point term sent to Coder	System	01 Aug 2020 03:17:36
User entered 'tinnitus'	Jared Bradshaw (b) (4)	01 Aug 2020 03:16:57
	(b) (4)	

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Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'un UNK 1965'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:16:57



US3162037

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:27:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:16:57

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Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:27:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:16:57

US3162037

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:16:57

**US3162037**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 15:27:33**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:16:57

**US3162037**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered 'Jan 1965'	System	01 Aug 2020 03:16:57

**US3162037**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered '1965'	System	01 Aug 2020 03:16:57

**US3162037**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered empty.	System	01 Aug 2020 03:16:57

**US3162037**

**Folder: Screening**

**Form: Medical History (18)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered empty.	System	01 Aug 2020 03:16:57



US3162037

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:27:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User coded data point as SOC: Psychiatric disorders, HLGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 03:18:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 03:18:17
Data point term sent to Coder	System	01 Aug 2020 03:17:36
User entered 'insomnia'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:17:16

**US3162037**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'un UNK 1999'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:17:16

US3162037

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:27:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:17:16

US3162037

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:27:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:17:16

US3162037

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:17:16

**US3162037**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 15:27:33**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:17:16

**US3162037**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered 'Jan 1999'	System	01 Aug 2020 03:17:16

**US3162037**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered '1999'	System	01 Aug 2020 03:17:16



**US3162037**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered empty.	System	01 Aug 2020 03:17:16

**US3162037**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered empty.	System	01 Aug 2020 03:17:16

US3162037

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:27:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User closed query 'Per DM CLR: Please specify the type of ASYMPTOMATIC BRADYCARDIA (e.g., sinus, ventricular, etc). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 19:49:19
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Sinus bradycardia, LLT: Sinus bradycardia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Sep 2020 11:06:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Sep 2020 11:06:45
Data point term sent to Coder	System	15 Sep 2020 05:56:43
Query 'Per DM CLR: Please specify the type of ASYMPTOMATIC BRADYCARDIA (e.g., sinus, ventricular, etc). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'UPDATED' (Site from DM).	Judith Kirstein (b) (4) (b) (4)	15 Sep 2020 05:56:21
Coding entries removed.	Judith Kirstein (b) (4) (b) (4)	15 Sep 2020 05:56:09
User entered 'ASYMPTOMATIC SINUS BRADYCARDIA' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	15 Sep 2020 05:56:09
User opened query 'Per DM CLR: Please specify the type of ASYMPTOMATIC BRADYCARDIA (e.g., sinus, ventricular, etc). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 07:22:31

US3162037

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:27:33

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Rate and rhythm disorders NEC, PT: Bradycardia, LLT: Bradycardia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Aug 2020 13:33:11
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Aug 2020 13:33:11
Data point term sent to Coder	System	01 Aug 2020 03:18:36
User entered 'asymptomatic bradycardia'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:17:39

US3162037

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'un UNK 2014'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:17:39

US3162037

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:27:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:17:39

US3162037

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:27:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:17:39

US3162037

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:17:39



US3162037

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:27:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:17:39

**US3162037**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered 'Jan 2014'	System	01 Aug 2020 03:17:39

**US3162037**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered '2014'	System	01 Aug 2020 03:17:39

**US3162037**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered empty.	System	01 Aug 2020 03:17:39

**US3162037**

**Folder: Screening**

**Form: Medical History (20)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered empty.	System	01 Aug 2020 03:17:39

US3162037

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 15:27:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Pain in hip - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Sep 2020 06:07:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Sep 2020 06:07:41
Data point term sent to Coder	System	15 Sep 2020 06:06:45
User entered 'RIGHT HIP PAIN'	Judith Kirstein (b) (4) (b) (4)	15 Sep 2020 06:06:03

**US3162037**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'UN Feb 2020'	Judith Kirstein (b) (4) (b) (4)	15 Sep 2020 06:06:03

**US3162037**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 09 Jun 2021 15:27:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '0'	Judith Kirstein (b) (4) (b) (4)	15 Sep 2020 06:06:03



**US3162037**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 09 Jun 2021 15:27:33**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	15 Sep 2020 06:06:03

US3162037

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered empty.	Judith Kirstein (b) (4) (b) (4)	15 Sep 2020 06:06:03

**US3162037**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 09 Jun 2021 15:27:33**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '0'	Judith Kirstein (b) (4) (b) (4)	15 Sep 2020 06:06:03

US3162037

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 15:27:33

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered 'Feb 2020'	System	15 Sep 2020 06:06:03

US3162037

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 15:27:33

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered '2020'	System	15 Sep 2020 06:06:03

**US3162037**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered empty.	System	15 Sep 2020 06:06:03

**US3162037**

**Folder: Screening**

**Form: Medical History (21)**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User entered empty.	System	15 Sep 2020 06:06:03

US3162037

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:20:45



**US3162037**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:27:33**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '31 Jul 2020'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:20:45

US3162037

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:33

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '12:53'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:20:45

**US3162037**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:27:33**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:54
User entered '31 Jul 2020 12:53'	System	01 Aug 2020 03:20:45

US3162037

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:33

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '69' in	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:20:45
DataPoint set to visible.	System	31 Jul 2020 22:07:05

US3162037

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:33

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '177.1' lb	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:20:45
DataPoint set to visible.	System	31 Jul 2020 22:07:05

US3162037

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:33

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:54
Amendment Manager: User entered '26.20778'	System	16 Sep 2020 23:40:03
User entered '26.2'	System	01 Aug 2020 03:20:45
DataPoint set to visible.	System	31 Jul 2020 22:07:05

US3162037

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:33

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:54
User entered 'kg/m2'	System	01 Aug 2020 03:20:45
DataPoint set to visible.	System	31 Jul 2020 22:07:05

US3162037

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. NOTE: Route is not required	(b) (4), (b) (6)	04 Sep 2020 02:47:35
' (Site from DM). Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. NOTE: Route is not required	Jourdan Manfred (b) (4) (b) (4)	03 Sep 2020 03:13:25
' answered with 'updated' (Site from DM). User entered missing code ND - Not Done; reason for change Data Entry Error	Jourdan Manfred (b) (4) (b) (4)	03 Sep 2020 03:13:18
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. NOTE: Route is not required	(b) (4), (b) (6)	31 Aug 2020 17:00:20
' (Site from DM). User entered '97.8' F	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:20:45



US3162037

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered empty; reason for change Data Entry Error	Jourdan Manfred (b) (4) (b) (4)	03 Sep 2020 03:13:18
User entered 'Oral (Oral)'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:20:45

US3162037

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:20:45

US3162037

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered missing code ND - Not Done; reason for change Data Entry Error	Jourdan Manfred (b) (4) (b) (4)	03 Sep 2020 03:13:18
User entered '55'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:20:45

**US3162037**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:27:33**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:54
User entered 'bpm'	System	01 Aug 2020 03:20:45

US3162037

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered missing code ND - Not Done; reason for change Data Entry Error	Jourdan Manfred (b) (4) (b) (4)	03 Sep 2020 03:13:18
User entered '16'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:20:45

US3162037

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:54
User entered 'breaths/min'	System	01 Aug 2020 03:20:45

US3162037

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered missing code ND - Not Done; reason for change Data Entry Error	Jourdan Manfred (b) (4) (b) (4)	03 Sep 2020 03:13:18
User entered '114'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:20:45

US3162037

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:54
User entered 'mmHg'	System	01 Aug 2020 03:20:45



US3162037

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered missing code ND - Not Done; reason for change Data Entry Error	Jourdan Manfred (b) (4) (b) (4)	03 Sep 2020 03:13:18
User entered '65'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:20:45

US3162037

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:33

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:54
User entered 'mmHg'	System	01 Aug 2020 03:20:45

US3162037

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:33

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:54

US3162037

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:33

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:54

US3162037

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:27:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:20:54

US3162037

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:27:33

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	07 Sep 2020 13:43:31
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		28 Aug 2020 20:53:05
User entered '31 Jul 2020'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:20:54

US3162037

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:27:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '31 Jul 2020'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:23:37

US3162037

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:27:33

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:23:37



US3162037

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:27:33

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:23:37

US3162037

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:27:33

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:23:37

US3162037

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:23:37

US3162037

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:27:33

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:23:37

US3162037

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'un UNK 2005'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:23:37

US3162037

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:27:33

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:23:37

US3162037

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:27:33

**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 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:24:00

US3162037

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:27:33

**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 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:24:00



US3162037

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:27:33

**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 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:24:00

US3162037

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:27:33

**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 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:24:00

US3162037

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:27:33

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 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:24:00

US3162037

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:27:33

[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 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:24:00

US3162037

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:27:33

**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 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:24:00

US3162037

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:27:33

**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 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:24:00

US3162037

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:27:33

[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 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:24:00

US3162037

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:27:33

**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 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:24:00



US3162037

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:27:33

**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 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:24:00

US3162037

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:27:33

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:24:00

US3162037

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:27:33

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'none'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:24:00

US3162037

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:27:33

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:24:00

US3162037

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:27:33

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:24:00

US3162037

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:27:33

**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 17:18:52
User signature succeeded.	(b) (4) Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:24:00

US3162037

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:27:33

[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 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:24:00

US3162037

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:27:33

**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 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:24:00



US3162037

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:27:33

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'I'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:24:00

US3162037

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:27:33

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:24:00

US3162037

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:27:33

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 03:24:00

**US3162037**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:27:33**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 19:26:34

**US3162037**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '31 Jul 2020'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 19:26:34

US3162037

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:27:33

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 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Aug 2020 19:26:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Aug 2020 19:26:38
User entered 'Clinic (Clinic)' reason for change: Data Entry Error	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 19:26:38
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Aug 2020 19:26:34
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 19:26:34

**US3162037**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:27:33**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User entered 'VISIT1'	System	01 Aug 2020 19:26:34

US3162037

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '31 JUL 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 20:09:30



US3162037

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:27:33

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 01:33:57
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:33:56
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	31 Jul 2020 20:09:30
User entered '184328' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 20:09:30

US3162037

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:27:33

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 20:09:30

US3162037

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:27:33

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 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:08:42

US3162037

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:27:33

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 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:08:42

US3162037

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:27:33

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:08:42

**US3162037**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 15:27:33**

**Diabetes (Type I, Type 2, or gestational)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:08:42

US3162037

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:27:33

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:08:42

US3162037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:27:33

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered missing code ND - Not Done; reason for change Data Entry Error	Jared Bradshaw (b) (4) (b) (4)	08 Aug 2020 20:02:18
User entered '69' in	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 19:32:27



US3162037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:27:33

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered missing code ND - Not Done; reason for change Data Entry Error	Jared Bradshaw (b) (4) (b) (4)	08 Aug 2020 20:02:18
User entered '175.3' lb	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 19:32:27

US3162037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:27:33

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered missing code ND - Not Done; reason for change Data Entry Error	Jared Bradshaw (b) (4) (b) (4)	08 Aug 2020 20:02:18
User entered '69' in	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 19:32:27

US3162037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:27:33

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered missing code ND - Not Done; reason for change Data Entry Error	Jared Bradshaw (b) (4) (b) (4)	08 Aug 2020 20:02:18
User entered '175.3' lb	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 19:32:27

US3162037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User accepted default value 'Pre-Dose (PREDOSE)'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 19:32:27

US3162037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 19:32:27

US3162037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '31 Jul 2020'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 19:32:27

**US3162037**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:27:33**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '12:53'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 19:32:27

**US3162037**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:27:33**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User entered '31 Jul 2020 12:53'	System	01 Aug 2020 19:32:27



US3162037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '97.8' F	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 19:32:27

US3162037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'Oral (Oral)'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 19:32:27

US3162037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 19:32:27

US3162037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '55'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 19:32:27

**US3162037**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:27:33**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User entered 'bpm'	System	01 Aug 2020 19:32:27

US3162037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '16'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 19:32:27

US3162037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User entered 'breaths/min'	System	01 Aug 2020 19:32:27

US3162037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '114'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 19:32:27



US3162037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User entered 'mmHg'	System	01 Aug 2020 19:32:27

US3162037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '65'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 19:32:27

US3162037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User entered 'mmHg'	System	01 Aug 2020 19:32:27

US3162037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:27:33

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered missing code ND - Not Done; reason for change Data Entry Error	Jared Bradshaw (b) (4) (b) (4)	08 Aug 2020 20:02:18
User entered '69' in	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 19:32:27

US3162037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:27:33

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4)	13 Feb 2021 01:35:19
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Jared Bradshaw (b) (4)	08 Aug 2020 20:02:18
User entered '175.3' lb	(b) (4)	
	Jared Bradshaw (b) (4)	01 Aug 2020 19:32:27
	(b) (4)	

US3162037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User accepted default value 'Post-Dose (POSTDOSE)'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 19:32:27

US3162037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 19:32:27

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '31 Jul 2020'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 19:32:27



US3162037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	18 Aug 2020 12:06:59
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).		01 Aug 2020 19:32:27
User entered '14:46'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 19:32:27

US3162037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User entered '31 Jul 2020 14:46'	System	01 Aug 2020 19:32:27

US3162037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '99.3' F	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 19:32:27

US3162037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'Oral (Oral)'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 19:32:27

US3162037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 19:32:27

US3162037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '57'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 19:32:27

US3162037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User entered 'bpm'	System	01 Aug 2020 19:32:27

US3162037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '16'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 19:32:27



US3162037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User entered 'breaths/min'	System	01 Aug 2020 19:32:27

US3162037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '129'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 19:32:27

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User entered 'mmHg'	System	01 Aug 2020 19:32:27

US3162037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '81'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 19:32:27

US3162037

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User entered 'mmHg'	System	01 Aug 2020 19:32:27

US3162037

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:27:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'No (N)' reason for change: Data Entry Error	Jared Bradshaw (b) (4) (b) (4)	08 Aug 2020 20:02:01
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 19:32:52

US3162037

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:27:33

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered empty; reason for change Data Entry Error	Jared Bradshaw (b) (4) (b) (4)	08 Aug 2020 20:02:01
User closed query 'Was the physical examination performed is Yes, however Date of examination is missing. Please provide.' (Site from System).	System	01 Aug 2020 19:33:00
User entered '31 Jul 2020' reason for change: Data Entry Error	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 19:33:00
User opened query 'Was the physical examination performed is Yes, however Date of examination is missing. Please provide.' (Site from System).	System	01 Aug 2020 19:32:52
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 19:32:52

US3162037

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:27:33

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	31 Jul 2020 22:07:27



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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:27:33

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	31 Jul 2020 22:07:27

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:27:33

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 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	31 Jul 2020 22:07:27

US3162037

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:27:33

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User entered 'MRNA-1273 OR PLACEBO'	System	31 Jul 2020 22:07:27

US3162037

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:27:33

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '31 Jul 2020'	Jared Bradshaw (b) (4) (b) (4)	31 Jul 2020 22:07:27

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:27:33

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '14:04'	Jared Bradshaw (b) (4) (b) (4)	31 Jul 2020 22:07:27

**US3162037**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:27:33**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User entered '31 Jul 2020 14:04'	System	31 Jul 2020 22:07:27

US3162037

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:27:33

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'Left Arm (LEFT ARM)'	Jared Bradshaw (b) (4) (b) (4)	31 Jul 2020 22:07:27

US3162037

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:27:33

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User entered 'ONCE'	System	31 Jul 2020 22:07:27



US3162037

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:27:33

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User entered 'INTRAMUSCULAR'	System	31 Jul 2020 22:07:27

US3162037

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:27:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 19:33:37

US3162037

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:27:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '31 Jul 2020'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 19:33:37

US3162037

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:27:33

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '13:55'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 19:33:37

**US3162037**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:27:33**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User entered '31 Jul 2020 13:55'	System	01 Aug 2020 19:33:37

US3162037

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:27:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '31 Jul 2020'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 19:35:34

**US3162037**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:27:33**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 19:35:34

US3162037

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:27:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 19:35:34



**US3162037**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:27:33**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '14:00'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 19:35:34

**US3162037**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:27:33**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User entered '31 Jul 2020 14:00'	System	01 Aug 2020 19:35:34

US3162037

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:27:33

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jared Bradshaw (b) (4)	01 Aug 2020 19:35:34

US3162037

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:27:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 19:35:34

US3162037

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:27:33

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 19:35:34

**US3162037**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:27:33**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User entered empty.	System	01 Aug 2020 19:35:34

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:27:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	01 Aug 2020 19:35:38

**US3162037**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:27:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User entered 'I'	System	01 Aug 2020 19:35:38



US3162037

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	31 Jul 2020 22:07:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Jul 2020 22:07:27

US3162037

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-07-31T15:47:44', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'b8c4c090-4ea1-4cfb-b6dc-04aa225b5b18' User entered 'Yes (Y)'	System	31 Jul 2020 22:48:06
	System	31 Jul 2020 22:48:06

US3162037

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-07-31T15:47:53', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'b8c4c090-4ea1-4cfd-b6dc-04aa225b5b18' User entered '99.8'	System	31 Jul 2020 22:48:06
	System	31 Jul 2020 22:48:06

US3162037

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-07-31T15:47:58', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'b8c4c090-4ea1-4cfb-b6dc-04aa225b5b18'	System	31 Jul 2020 22:48:06
User entered 'No (N)'	System	31 Jul 2020 22:48:06

**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-07-31T15:48:03', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'b8c4c090-4ea1-4cfd-b6dc-04aa225b5b18' User entered '31 Jul 2020 15:48'	System	31 Jul 2020 22:48:06
	System	31 Jul 2020 22:48:06

US3162037

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '31 Jul 2020 14:24'	System	31 Jul 2020 22:07:27

US3162037

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '31 Jul 2020 16:54'	System	31 Jul 2020 22:07:27

US3162037

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	31 Jul 2020 22:07:27
User entered 'Day 1, after vaccination (at home)'	System	31 Jul 2020 22:07:27



US3162037

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-01T09:23:03', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '6e64f124-e859-4a46-ac6c-dc8e7db33348' User entered 'Yes (Y)'	System	01 Aug 2020 16:23:23
	System	01 Aug 2020 16:23:23

US3162037

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-01T09:23:11', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '6e64f124-e859-4a46-ac6c-dc8e7db33348' User entered '98.5'	System	01 Aug 2020 16:23:23
	System	01 Aug 2020 16:23:23

US3162037

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-01T09:23:16', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '6e64f124-e859-4a46-ac6c-dc8e7db33348'	System	01 Aug 2020 16:23:23
User entered 'No (N)'	System	01 Aug 2020 16:23:23

**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-01T09:23:21', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '6e64f124-e859-4a46-ac6c-dc8e7db33348' User entered '01 Aug 2020 09:23'	System	01 Aug 2020 16:23:23
	System	01 Aug 2020 16:23:23

US3162037

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '31 Jul 2020 17:49'	System	31 Jul 2020 22:07:27

US3162037

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '01 Aug 2020 11:59'	System	31 Jul 2020 22:07:27

US3162037

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	31 Jul 2020 22:07:27
User entered 'Day 2'	System	31 Jul 2020 22:07:27

US3162037

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:27:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-01T14:45:57', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '7e435be4-fdb1-41b7-8a52-de280f185877'	System	01 Aug 2020 21:46:43
User entered 'Yes (Y)'	System	01 Aug 2020 21:46:43



US3162037

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:27:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-01T14:46:04', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '7e435be4-fdb1-41b7-8a52-de280f185877' User entered '99.0'	System	01 Aug 2020 21:46:43
	System	01 Aug 2020 21:46:43

US3162037

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-01T14:46:09', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '7e435be4-fdb1-41b7-8a52-de280f185877'	System	01 Aug 2020 21:46:43
User entered 'No (N)'	System	01 Aug 2020 21:46:43

**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-01T14:46:41', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '7e435be4-fdb1-41b7-8a52-de280f185877'	System	01 Aug 2020 21:46:43
User entered '01 Aug 2020 14:46'	System	01 Aug 2020 21:46:43

US3162037

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:27:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '01 Aug 2020 12:00'	System	31 Jul 2020 22:07:27

US3162037

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:27:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '02 Aug 2020 11:59'	System	31 Jul 2020 22:07:27

US3162037

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	31 Jul 2020 22:07:27
User entered 'Day 3'	System	31 Jul 2020 22:07:27

US3162037

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:27:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-02T20:50:57', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '9d15b7c5-0979-4127-a5a2-e911b97a134a' User entered 'Yes (Y)'	System	03 Aug 2020 03:51:18
	System	03 Aug 2020 03:51:18

US3162037

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:27:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-02T20:51:03', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '9d15b7c5-0979-4127-a5a2-e911b97a134a' User entered '98.6'	System	03 Aug 2020 03:51:18
	System	03 Aug 2020 03:51:18



US3162037

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-02T20:51:11', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '9d15b7c5-0979-4127-a5a2-e911b97a134a'	System	03 Aug 2020 03:51:18
User entered 'No (N)'	System	03 Aug 2020 03:51:18

**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-02T20:51:16', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '9d15b7c5-0979-4127-a5a2-e911b97a134a' User entered '02 Aug 2020 20:51'	System	03 Aug 2020 03:51:18
	System	03 Aug 2020 03:51:18

US3162037

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:27:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '02 Aug 2020 12:00'	System	31 Jul 2020 22:07:27

US3162037

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:27:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '03 Aug 2020 11:59'	System	31 Jul 2020 22:07:27

US3162037

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	31 Jul 2020 22:07:27
User entered 'Day 4'	System	31 Jul 2020 22:07:27

US3162037

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:27:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-03T20:31:06', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '0f120d27-fb3e-40c8-b0e7-5a160621f2c7' User entered 'Yes (Y)'	System	04 Aug 2020 03:31:24
	System	04 Aug 2020 03:31:24

US3162037

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:27:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-03T20:31:14', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '0f120d27-fb3e-40c8-b0e7-5a160621f2c7' User entered '98.2'	System	04 Aug 2020 03:31:24
	System	04 Aug 2020 03:31:24

US3162037

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-03T20:31:18', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '0f120d27-fb3e-40c8-b0e7-5a160621f2c7'	System	04 Aug 2020 03:31:24
User entered 'No (N)'	System	04 Aug 2020 03:31:24



**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-03T20:31:21', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '0f120d27-fb3e-40c8-b0e7-5a160621f2c7' User entered '03 Aug 2020 20:31'	System	04 Aug 2020 03:31:24
	System	04 Aug 2020 03:31:24

US3162037

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:27:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '03 Aug 2020 12:00'	System	31 Jul 2020 22:07:27

US3162037

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:27:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '04 Aug 2020 11:59'	System	31 Jul 2020 22:07:27

US3162037

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	31 Jul 2020 22:07:27
User entered 'Day 5'	System	31 Jul 2020 22:07:27

US3162037

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:27:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-04T21:17:39', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'f0a73c46-2f25-4e0d-87e3-d6f2fc877cb2'	System	05 Aug 2020 04:17:59
User entered 'Yes (Y)'	System	05 Aug 2020 04:17:59

US3162037

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:27:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-04T21:17:49', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'f0a73c46-2f25-4e0d-87e3-d6f2fc877cb2' User entered '98.0'	System	05 Aug 2020 04:17:59
	System	05 Aug 2020 04:17:59

US3162037

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-04T21:17:53', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'f0a73c46-2f25-4e0d-87e3-d6f2fc877cb2'	System	05 Aug 2020 04:17:59
User entered 'No (N)'	System	05 Aug 2020 04:17:59

**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-04T21:17:57', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'f0a73c46-2f25-4e0d-87e3-d6f2fc877cb2'	System	05 Aug 2020 04:17:59
User entered '04 Aug 2020 21:17'	System	05 Aug 2020 04:17:59



US3162037

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:27:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '04 Aug 2020 12:00'	System	31 Jul 2020 22:07:27

US3162037

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:27:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '05 Aug 2020 11:59'	System	31 Jul 2020 22:07:27

US3162037

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	31 Jul 2020 22:07:27
User entered 'Day 6'	System	31 Jul 2020 22:07:27

US3162037

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:27:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-05T20:52:00', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'c0b6e51f-eeda-4d9e-8d0a-a6b463381ed6' User entered 'Yes (Y)'	System	06 Aug 2020 03:52:25
	System	06 Aug 2020 03:52:25

US3162037

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:27:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-05T20:52:08', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'c0b6e51f-eeda-4d9e-8d0a-a6b463381ed6' User entered '99.7'	System	06 Aug 2020 03:52:25
	System	06 Aug 2020 03:52:25

US3162037

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-05T20:52:20', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'c0b6e51f-eeda-4d9e-8d0a-a6b463381ed6'	System	06 Aug 2020 03:52:25
User entered 'No (N)'	System	06 Aug 2020 03:52:25

**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-05T20:52:23', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'c0b6e51f-eeda-4d9e-8d0a-a6b463381ed6' User entered '05 Aug 2020 20:52'	System	06 Aug 2020 03:52:25
	System	06 Aug 2020 03:52:25

US3162037

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:27:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '05 Aug 2020 12:00'	System	31 Jul 2020 22:07:27



US3162037

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:27:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '06 Aug 2020 11:59'	System	31 Jul 2020 22:07:27

US3162037

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	31 Jul 2020 22:07:27
User entered 'Day 7'	System	31 Jul 2020 22:07:27

US3162037

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:27:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-06T20:45:49', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '40166c3c-024d-4a5e-adf4-dfdf56c95c87'	System	07 Aug 2020 03:46:07
User entered 'Yes (Y)'	System	07 Aug 2020 03:46:07

US3162037

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:27:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-06T20:45:59', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '40166c3c-024d-4a5e-adf4-dfdf56c95c87' User entered '98.0'	System	07 Aug 2020 03:46:07
	System	07 Aug 2020 03:46:07

US3162037

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-06T20:46:02', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '40166c3c-024d-4a5e-adf4-dfdf56c95c87'	System	07 Aug 2020 03:46:07
User entered 'No (N)'	System	07 Aug 2020 03:46:07

**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-06T20:46:05', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '40166c3c-024d-4a5e-adf4-dfdf56c95c87'	System	07 Aug 2020 03:46:07
User entered '06 Aug 2020 20:46'	System	07 Aug 2020 03:46:07

US3162037

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:27:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '06 Aug 2020 12:00'	System	31 Jul 2020 22:07:27

US3162037

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:27:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '07 Aug 2020 11:59'	System	31 Jul 2020 22:07:27



US3162037

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	31 Jul 2020 22:07:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Jul 2020 22:07:27

US3162037

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-07-31T15:48:30', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'b36b06fb-bd0a-434b-a79d-e9e013768955' User entered 'None (1)'	System	31 Jul 2020 22:49:07
	System	31 Jul 2020 22:49:07

US3162037

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-07-31T15:48:45', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'b36b06fb-bd0a-434b-a79d-e9e013768955' User entered 'No (N)'	System	31 Jul 2020 22:49:07
	System	31 Jul 2020 22:49:07

US3162037

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-07-31T15:48:50', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'b36b06fb-bd0a-434b-a79d-e9e013768955'	System	31 Jul 2020 22:49:07
User entered 'No (N)'	System	31 Jul 2020 22:49:07

US3162037

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-07-31T15:48:58', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'b36b06fb-bd0a-434b-a79d-e9e013768955'	System	31 Jul 2020 22:49:07
User entered 'None (1)'	System	31 Jul 2020 22:49:07

**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-07-31T15:49:03', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'b36b06fb-bd0a-434b-a79d-e9e013768955'	System	31 Jul 2020 22:49:07
User entered '31 Jul 2020 15:49'	System	31 Jul 2020 22:49:07

US3162037

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '31 Jul 2020 14:24'	System	31 Jul 2020 22:07:27

**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '31 Jul 2020 16:54'	System	31 Jul 2020 22:07:27



US3162037

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	31 Jul 2020 22:07:27
User entered 'Day 1, after vaccination (at home)'	System	31 Jul 2020 22:07:27

US3162037

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-01T09:23:27', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '50830997-3310-4eca-9dab-fe891ec5de2c' User entered 'None (1)'	System	01 Aug 2020 16:23:44
	System	01 Aug 2020 16:23:44

US3162037

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-01T09:23:31', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '50830997-3310-4eca-9dab-fe891ec5de2c' User entered 'No (N)'	System	01 Aug 2020 16:23:44
	System	01 Aug 2020 16:23:44

US3162037

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-01T09:23:34', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '50830997-3310-4eca-9dab-fe891ec5de2c' User entered 'No (N)'	System	01 Aug 2020 16:23:44
	System	01 Aug 2020 16:23:44

US3162037

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-01T09:23:39', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '50830997-3310-4eca-9dab-fe891ec5de2c' User entered 'None (1)'	System	01 Aug 2020 16:23:44
	System	01 Aug 2020 16:23:44

**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-01T09:23:42', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '50830997-3310-4eca-9dab-fe891ec5de2c' User entered '01 Aug 2020 09:23'	System	01 Aug 2020 16:23:44
	System	01 Aug 2020 16:23:44

US3162037

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '31 Jul 2020 17:49'	System	31 Jul 2020 22:07:27

US3162037

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '01 Aug 2020 11:59'	System	31 Jul 2020 22:07:27



US3162037

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	31 Jul 2020 22:07:27
User entered 'Day 2'	System	31 Jul 2020 22:07:27

US3162037

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:27:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-01T14:43:52', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'c0c98351-469c-4b50-bc40-5246e46df4b2'	System	01 Aug 2020 21:44:13
User entered 'None (1)'	System	01 Aug 2020 21:44:13

US3162037

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:27:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-01T14:43:56', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'c0c98351-469c-4b50-bc40-5246e46df4b2'	System	01 Aug 2020 21:44:13
User entered 'No (N)'	System	01 Aug 2020 21:44:13

US3162037

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-01T14:44:01', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'c0c98351-469c-4b50-bc40-5246e46df4b2'	System	01 Aug 2020 21:44:13
User entered 'No (N)'	System	01 Aug 2020 21:44:13

US3162037

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:27:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-01T14:44:06', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'c0c98351-469c-4b50-bc40-5246e46df4b2'	System	01 Aug 2020 21:44:13
User entered 'None (1)'	System	01 Aug 2020 21:44:13

**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-01T14:44:11', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'c0c98351-469c-4b50-bc40-5246e46df4b2' User entered '01 Aug 2020 14:44'	System	01 Aug 2020 21:44:13
	System	01 Aug 2020 21:44:13

US3162037

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:27:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '01 Aug 2020 12:00'	System	31 Jul 2020 22:07:27

US3162037

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:27:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '02 Aug 2020 11:59'	System	31 Jul 2020 22:07:27



US3162037

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	31 Jul 2020 22:07:27
User entered 'Day 3'	System	31 Jul 2020 22:07:27

US3162037

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:27:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-02T20:50:10', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '1ae06798-327e-4d3e-b8ea-bcce6c70bb1c' User entered 'None (1)'	System	03 Aug 2020 03:50:32
	System	03 Aug 2020 03:50:32

US3162037

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:27:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-02T20:50:14', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '1ae06798-327e-4d3e-b8ea-bcce6c70bb1c' User entered 'No (N)'	System	03 Aug 2020 03:50:32
	System	03 Aug 2020 03:50:32

US3162037

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-02T20:50:21', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '1ae06798-327e-4d3e-b8ea-bcce6c70bb1c' User entered 'No (N)'	System	03 Aug 2020 03:50:32
	System	03 Aug 2020 03:50:32

US3162037

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:27:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-02T20:50:25', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '1ae06798-327e-4d3e-b8ea-bcce6c70bb1c' User entered 'None (1)'	System	03 Aug 2020 03:50:32
	System	03 Aug 2020 03:50:32

**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-02T20:50:28', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '1ae06798-327e-4d3e-b8ea-bcce6c70bb1c' User entered '02 Aug 2020 20:50'	System	03 Aug 2020 03:50:32
	System	03 Aug 2020 03:50:32

US3162037

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:27:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '02 Aug 2020 12:00'	System	31 Jul 2020 22:07:27

US3162037

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:27:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '03 Aug 2020 11:59'	System	31 Jul 2020 22:07:27



US3162037

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	31 Jul 2020 22:07:27
User entered 'Day 4'	System	31 Jul 2020 22:07:27

US3162037

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:27:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-03T20:28:29', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '8589005a-0d6c-4c99-b208-029c75d8b05f' User entered 'None (1)'	System	04 Aug 2020 03:28:47
	System	04 Aug 2020 03:28:47

US3162037

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:27:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-03T20:28:33', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '8589005a-0d6c-4c99-b208-029c75d8b05f' User entered 'No (N)'	System	04 Aug 2020 03:28:47
	System	04 Aug 2020 03:28:47

US3162037

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-03T20:28:36', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '8589005a-0d6c-4c99-b208-029c75d8b05f' User entered 'No (N)'	System	04 Aug 2020 03:28:47
	System	04 Aug 2020 03:28:47

US3162037

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:27:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-03T20:28:40', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '8589005a-0d6c-4c99-b208-029c75d8b05f' User entered 'None (1)'	System	04 Aug 2020 03:28:47
	System	04 Aug 2020 03:28:47

**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-03T20:28:44', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '8589005a-0d6c-4c99-b208-029c75d8b05f' User entered '03 Aug 2020 20:28'	System	04 Aug 2020 03:28:47
	System	04 Aug 2020 03:28:47

US3162037

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:27:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '03 Aug 2020 12:00'	System	31 Jul 2020 22:07:27

US3162037

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:27:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '04 Aug 2020 11:59'	System	31 Jul 2020 22:07:27



US3162037

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	31 Jul 2020 22:07:27
User entered 'Day 5'	System	31 Jul 2020 22:07:27

US3162037

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:27:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-04T21:16:04', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '25e6efc4-aaa6-42f3-b95b-7e1f3b93d9c4' User entered 'None (1)'	System	05 Aug 2020 04:16:19
	System	05 Aug 2020 04:16:19

US3162037

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:27:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-04T21:16:07', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '25e6efc4-aaa6-42f3-b95b-7e1f3b93d9c4'	System	05 Aug 2020 04:16:19
User entered 'No (N)'	System	05 Aug 2020 04:16:19

US3162037

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-04T21:16:09', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '25e6efc4-aaa6-42f3-b95b-7e1f3b93d9c4' User entered 'No (N)'	System	05 Aug 2020 04:16:19
	System	05 Aug 2020 04:16:19

US3162037

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:27:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-04T21:16:12', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '25e6efc4-aaa6-42f3-b95b-7e1f3b93d9c4'	System	05 Aug 2020 04:16:19
User entered 'None (1)'	System	05 Aug 2020 04:16:19

**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-04T21:16:16', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '25e6efc4-aaa6-42f3-b95b-7e1f3b93d9c4' User entered '04 Aug 2020 21:16'	System	05 Aug 2020 04:16:19
	System	05 Aug 2020 04:16:19

US3162037

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:27:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '04 Aug 2020 12:00'	System	31 Jul 2020 22:07:27

US3162037

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:27:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '05 Aug 2020 11:59'	System	31 Jul 2020 22:07:27



US3162037

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	31 Jul 2020 22:07:27
User entered 'Day 6'	System	31 Jul 2020 22:07:27

US3162037

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:27:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-05T20:51:19', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '8efd03d5-e2af-41cc-8c00-a91e12fc9359'	System	06 Aug 2020 03:51:40
User entered 'None (1)'	System	06 Aug 2020 03:51:40

US3162037

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:27:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-05T20:51:26', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '8efd03d5-e2af-41cc-8c00-a91e12fc9359'	System	06 Aug 2020 03:51:40
User entered 'No (N)'	System	06 Aug 2020 03:51:40

US3162037

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-05T20:51:29', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '8efd03d5-e2af-41cc-8c00-a91e12fc9359'	System	06 Aug 2020 03:51:40
User entered 'No (N)'	System	06 Aug 2020 03:51:40

US3162037

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:27:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-05T20:51:35', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '8efd03d5-e2af-41cc-8c00-a91e12fc9359'	System	06 Aug 2020 03:51:40
User entered 'None (1)'	System	06 Aug 2020 03:51:40

**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-05T20:51:38', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '8efd03d5-e2af-41cc-8c00-a91e12fc9359'	System	06 Aug 2020 03:51:40
User entered '05 Aug 2020 20:51'	System	06 Aug 2020 03:51:40

US3162037

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:27:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '05 Aug 2020 12:00'	System	31 Jul 2020 22:07:27

US3162037

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:27:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '06 Aug 2020 11:59'	System	31 Jul 2020 22:07:27



US3162037

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	31 Jul 2020 22:07:27
User entered 'Day 7'	System	31 Jul 2020 22:07:27

US3162037

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:27:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-06T20:44:43', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '780cda66-05f6-4b4d-b10c-06ec6b6080fd' User entered 'None (1)'	System	07 Aug 2020 03:45:02
	System	07 Aug 2020 03:45:02

US3162037

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:27:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-06T20:44:46', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '780cda66-05f6-4b4d-b10c-06ec6b6080fd' User entered 'No (N)'	System	07 Aug 2020 03:45:02
	System	07 Aug 2020 03:45:02

US3162037

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-06T20:44:50', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '780cda66-05f6-4b4d-b10c-06ec6b6080fd' User entered 'No (N)'	System	07 Aug 2020 03:45:02
	System	07 Aug 2020 03:45:02

US3162037

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:27:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-06T20:44:54', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '780cda66-05f6-4b4d-b10c-06ec6b6080fd' User entered 'None (1)'	System	07 Aug 2020 03:45:02
	System	07 Aug 2020 03:45:02

**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-06T20:44:56', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '780cda66-05f6-4b4d-b10c-06ec6b6080fd' User entered '06 Aug 2020 20:44'	System	07 Aug 2020 03:45:02
	System	07 Aug 2020 03:45:02

US3162037

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:27:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '06 Aug 2020 12:00'	System	31 Jul 2020 22:07:27

**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '07 Aug 2020 11:59'	System	31 Jul 2020 22:07:27



US3162037

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	31 Jul 2020 22:07:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Jul 2020 22:07:27

US3162037

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-07-31T15:49:27', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'e6954c70-1892-4be5-b33c-a5a7179d0202' User entered 'None (0)'	System	31 Jul 2020 22:50:10
	System	31 Jul 2020 22:50:10

**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:27:33**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-07-31T15:49:32', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'e6954c70-1892-4be5-b33c-a5a7179d0202' User entered 'None (0)'	System	31 Jul 2020 22:50:10
	System	31 Jul 2020 22:50:10

US3162037

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-07-31T15:49:36', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'e6954c70-1892-4be5-b33c-a5a7179d0202' User entered 'None (0)'	System	31 Jul 2020 22:50:10
	System	31 Jul 2020 22:50:10

US3162037

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-07-31T15:49:39', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'e6954c70-1892-4be5-b33c-a5a7179d0202' User entered 'None (0)'	System	31 Jul 2020 22:50:10
	System	31 Jul 2020 22:50:10

**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:27:33**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-07-31T15:49:43', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'e6954c70-1892-4be5-b33c-a5a7179d0202' User entered 'None (0)'	System	31 Jul 2020 22:50:10
	System	31 Jul 2020 22:50:10

US3162037

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-07-31T15:49:53', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'e6954c70-1892-4be5-b33c-a5a7179d0202' User entered 'None (0)'	System	31 Jul 2020 22:50:10
	System	31 Jul 2020 22:50:10

US3162037

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

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)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-07-31T15:50:02', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'e6954c70-1892-4be5-b33c-a5a7179d0202' User entered 'No (N)'	System	31 Jul 2020 22:50:10
	System	31 Jul 2020 22:50:10



**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-07-31T15:50:08', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'e6954c70-1892-4be5-b33c-a5a7179d0202'	System	31 Jul 2020 22:50:10
User entered '31 Jul 2020 15:50'	System	31 Jul 2020 22:50:10

US3162037

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '31 Jul 2020 14:24'	System	31 Jul 2020 22:07:27

**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '31 Jul 2020 16:54'	System	31 Jul 2020 22:07:27

US3162037

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	31 Jul 2020 22:07:27
User entered 'Day 1, after vaccination (at home)'	System	31 Jul 2020 22:07:27

US3162037

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-01T09:23:54', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'a57b0756-e75f-4696-887d-e8192838b0c2' User entered 'None (0)'	System	01 Aug 2020 16:24:35
	System	01 Aug 2020 16:24:35

**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:27:33**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-01T09:24:03', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'a57b0756-e75f-4696-887d-e8192838b0c2' User entered 'None (0)'	System	01 Aug 2020 16:24:35
	System	01 Aug 2020 16:24:35

US3162037

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-01T09:24:12', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'a57b0756-e75f-4696-887d-e8192838b0c2' User entered 'None (0)'	System	01 Aug 2020 16:24:35
	System	01 Aug 2020 16:24:35

US3162037

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-01T09:24:15', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'a57b0756-e75f-4696-887d-e8192838b0c2' User entered 'None (0)'	System	01 Aug 2020 16:24:35
	System	01 Aug 2020 16:24:35



**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:27:33**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-01T09:24:22', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'a57b0756-e75f-4696-887d-e8192838b0c2' User entered 'None (0)'	System	01 Aug 2020 16:24:35
	System	01 Aug 2020 16:24:35

**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:27:33**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-01T09:24:25', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'a57b0756-e75f-4696-887d-e8192838b0c2' User entered 'None (0)'	System	01 Aug 2020 16:24:35
	System	01 Aug 2020 16:24:35

US3162037

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

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)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-01T09:24:30', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'a57b0756-e75f-4696-887d-e8192838b0c2'	System	01 Aug 2020 16:24:35
User entered 'No (N)'	System	01 Aug 2020 16:24:35

**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-01T09:24:33', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'a57b0756-e75f-4696-887d-e8192838b0c2'	System	01 Aug 2020 16:24:35
User entered '01 Aug 2020 09:24'	System	01 Aug 2020 16:24:35

US3162037

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '31 Jul 2020 17:49'	System	31 Jul 2020 22:07:27

US3162037

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '01 Aug 2020 11:59'	System	31 Jul 2020 22:07:27

US3162037

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	31 Jul 2020 22:07:27
User entered 'Day 2'	System	31 Jul 2020 22:07:27

US3162037

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:27:33

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-01T14:44:27', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'f8091ca0-6e20-45c5-af44-955ad1195ae6' User entered 'None (0)'	System	01 Aug 2020 21:45:39
	System	01 Aug 2020 21:45:39



US3162037

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:27:33

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-01T14:45:06', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'f8091ca0-6e20-45c5-af44-955ad1195ae6' User entered 'None (0)'	System	01 Aug 2020 21:45:39
	System	01 Aug 2020 21:45:39

US3162037

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:27:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-01T14:45:12', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'f8091ca0-6e20-45c5-af44-955ad1195ae6' User entered 'None (0)'	System	01 Aug 2020 21:45:39
	System	01 Aug 2020 21:45:39

US3162037

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:27:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-01T14:45:16', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'f8091ca0-6e20-45c5-af44-955ad1195ae6' User entered 'None (0)'	System	01 Aug 2020 21:45:39
	System	01 Aug 2020 21:45:39

**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:27:33**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-01T14:45:22', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'f8091ca0-6e20-45c5-af44-955ad1195ae6' User entered 'None (0)'	System	01 Aug 2020 21:45:39
	System	01 Aug 2020 21:45:39

US3162037

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:27:33

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-01T14:45:26', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'f8091ca0-6e20-45c5-af44-955ad1195ae6' User entered 'None (0)'	System	01 Aug 2020 21:45:39
	System	01 Aug 2020 21:45:39

US3162037

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:27:33

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)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-01T14:45:30', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'f8091ca0-6e20-45c5-af44-955ad1195ae6' User entered 'No (N)'	System	01 Aug 2020 21:45:39
	System	01 Aug 2020 21:45:39

**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-01T14:45:35', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'f8091ca0-6e20-45c5-af44-955ad1195ae6' User entered '01 Aug 2020 14:45'	System	01 Aug 2020 21:45:39
	System	01 Aug 2020 21:45:39

US3162037

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:27:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '01 Aug 2020 12:00'	System	31 Jul 2020 22:07:27



US3162037

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:27:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '02 Aug 2020 11:59'	System	31 Jul 2020 22:07:27

US3162037

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	31 Jul 2020 22:07:27
User entered 'Day 3'	System	31 Jul 2020 22:07:27

**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:27:33**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-02T20:49:01', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '8ed68acb-2429-46ec-a2a0-198ed79b9512' User entered 'None (0)'	System	03 Aug 2020 03:49:53
	System	03 Aug 2020 03:49:53

**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:27:33**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-02T20:49:14', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '8ed68acb-2429-46ec-a2a0-198ed79b9512'	System	03 Aug 2020 03:49:53
User entered 'Some interference with activity (2)'	System	03 Aug 2020 03:49:53

US3162037

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:27:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-02T20:49:21', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '8ed68acb-2429-46ec-a2a0-198ed79b9512'	System	03 Aug 2020 03:49:53
User entered 'No interference with activity (1)'	System	03 Aug 2020 03:49:53

US3162037

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:27:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-02T20:49:28', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '8ed68acb-2429-46ec-a2a0-198ed79b9512' User entered 'None (0)'	System	03 Aug 2020 03:49:53
	System	03 Aug 2020 03:49:53

**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:27:33**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-02T20:49:40', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '8ed68acb-2429-46ec-a2a0-198ed79b9512'	System	03 Aug 2020 03:49:53
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	03 Aug 2020 03:49:53

**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:27:33**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-02T20:49:44', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '8ed68acb-2429-46ec-a2a0-198ed79b9512' User entered 'None (0)'	System	03 Aug 2020 03:49:53
	System	03 Aug 2020 03:49:53



US3162037

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:27:33

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)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-02T20:49:47', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '8ed68acb-2429-46ec-a2a0-198ed79b9512' User entered 'No (N)'	System	03 Aug 2020 03:49:53
	System	03 Aug 2020 03:49:53

**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-02T20:49:50', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '8ed68acb-2429-46ec-a2a0-198ed79b9512' User entered '02 Aug 2020 20:49'	System	03 Aug 2020 03:49:53
	System	03 Aug 2020 03:49:53

**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '02 Aug 2020 12:00'	System	31 Jul 2020 22:07:27

US3162037

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:27:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '03 Aug 2020 11:59'	System	31 Jul 2020 22:07:27

US3162037

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	31 Jul 2020 22:07:27
User entered 'Day 4'	System	31 Jul 2020 22:07:27

**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:27:33**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-03T20:27:28', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '8345c66a-1ca0-4e17-9bf7-e17c72f1eb2f' User entered 'None (0)'	System	04 Aug 2020 03:28:12
	System	04 Aug 2020 03:28:12

**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:27:33**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-03T20:27:38', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '8345c66a-1ca0-4e17-9bf7-e17c72f1eb2f'	System	04 Aug 2020 03:28:12
User entered 'Some interference with activity (2)'	System	04 Aug 2020 03:28:12

**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:27:33**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-03T20:27:44', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '8345c66a-1ca0-4e17-9bf7-e17c72f1eb2f' User entered 'Some interference with activity (2)'	System	04 Aug 2020 03:28:12
	System	04 Aug 2020 03:28:12



US3162037

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:27:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-03T20:27:54', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '8345c66a-1ca0-4e17-9bf7-e17c72f1eb2f' User entered 'No interference with activity (1)'	System	04 Aug 2020 03:28:12
	System	04 Aug 2020 03:28:12

**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:27:33**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-03T20:28:00', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '8345c66a-1ca0-4e17-9bf7-e17c72f1eb2f' User entered 'None (0)'	System	04 Aug 2020 03:28:12
	System	04 Aug 2020 03:28:12

US3162037

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:27:33

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-03T20:28:03', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '8345c66a-1ca0-4e17-9bf7-e17c72f1eb2f' User entered 'None (0)'	System	04 Aug 2020 03:28:12
	System	04 Aug 2020 03:28:12

US3162037

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:27:33

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)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-03T20:28:07', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '8345c66a-1ca0-4e17-9bf7-e17c72f1eb2f' User entered 'No (N)'	System	04 Aug 2020 03:28:12
	System	04 Aug 2020 03:28:12

**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-03T20:28:10', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '8345c66a-1ca0-4e17-9bf7-e17c72f1eb2f' User entered '03 Aug 2020 20:28'	System	04 Aug 2020 03:28:12
	System	04 Aug 2020 03:28:12

US3162037

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:27:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '03 Aug 2020 12:00'	System	31 Jul 2020 22:07:27

US3162037

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:27:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '04 Aug 2020 11:59'	System	31 Jul 2020 22:07:27

US3162037

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	31 Jul 2020 22:07:27
User entered 'Day 5'	System	31 Jul 2020 22:07:27



**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:27:33**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-04T21:15:22', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'f35a158b-4ab2-482b-911e-5153e4f6cbe8' User entered 'None (0)'	System	05 Aug 2020 04:15:54
	System	05 Aug 2020 04:15:54

**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:27:33**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-04T21:15:26', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'f35a158b-4ab2-482b-911e-5153e4f6cbe8' User entered 'None (0)'	System	05 Aug 2020 04:15:54
	System	05 Aug 2020 04:15:54

US3162037

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:27:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-04T21:15:31', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'f35a158b-4ab2-482b-911e-5153e4f6cbe8' User entered 'None (0)'	System	05 Aug 2020 04:15:54
	System	05 Aug 2020 04:15:54

US3162037

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:27:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-04T21:15:38', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'f35a158b-4ab2-482b-911e-5153e4f6cbe8' User entered 'None (0)'	System	05 Aug 2020 04:15:54
	System	05 Aug 2020 04:15:54

**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:27:33**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-04T21:15:43', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'f35a158b-4ab2-482b-911e-5153e4f6cbe8' User entered 'None (0)'	System	05 Aug 2020 04:15:54
	System	05 Aug 2020 04:15:54

**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:27:33**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-04T21:15:46', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'f35a158b-4ab2-482b-911e-5153e4f6cbe8' User entered 'None (0)'	System	05 Aug 2020 04:15:54
	System	05 Aug 2020 04:15:54

US3162037

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:27:33

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)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-04T21:15:49', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'f35a158b-4ab2-482b-911e-5153e4f6cbe8' User entered 'No (N)'	System	05 Aug 2020 04:15:54
	System	05 Aug 2020 04:15:54

**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-04T21:15:53', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'f35a158b-4ab2-482b-911e-5153e4f6cbe8' User entered '04 Aug 2020 21:15'	System	05 Aug 2020 04:15:54
	System	05 Aug 2020 04:15:54



**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '04 Aug 2020 12:00'	System	31 Jul 2020 22:07:27

US3162037

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:27:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '05 Aug 2020 11:59'	System	31 Jul 2020 22:07:27

**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	31 Jul 2020 22:07:27
User entered 'Day 6'	System	31 Jul 2020 22:07:27

**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:27:33**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-05T20:50:30', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'c40de47b-3b1e-4dba-8a7b-600b553aca7d' User entered 'None (0)'	System	06 Aug 2020 03:51:06
	System	06 Aug 2020 03:51:06

**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:27:33**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-05T20:50:33', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'c40de47b-3b1e-4dba-8a7b-600b553aca7d' User entered 'None (0)'	System	06 Aug 2020 03:51:06
	System	06 Aug 2020 03:51:06

US3162037

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:27:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-05T20:50:40', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'c40de47b-3b1e-4dba-8a7b-600b553aca7d'	System	06 Aug 2020 03:51:06
User entered 'No interference with activity (1)'	System	06 Aug 2020 03:51:06

US3162037

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:27:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-05T20:50:46', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'c40de47b-3b1e-4dba-8a7b-600b553aca7d' User entered 'No interference with activity (1)'	System	06 Aug 2020 03:51:06
	System	06 Aug 2020 03:51:06

**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:27:33**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-05T20:50:53', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'c40de47b-3b1e-4dba-8a7b-600b553aca7d'	System	06 Aug 2020 03:51:06
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	06 Aug 2020 03:51:06



**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:27:33**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-05T20:50:56', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'c40de47b-3b1e-4dba-8a7b-600b553aca7d' User entered 'None (0)'	System	06 Aug 2020 03:51:06
	System	06 Aug 2020 03:51:06

US3162037

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:27:33

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)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-05T20:50:59', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'c40de47b-3b1e-4dba-8a7b-600b553aca7d' User entered 'No (N)'	System	06 Aug 2020 03:51:06
	System	06 Aug 2020 03:51:06

**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-05T20:51:02', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'c40de47b-3b1e-4dba-8a7b-600b553aca7d' User entered '05 Aug 2020 20:51'	System	06 Aug 2020 03:51:06
	System	06 Aug 2020 03:51:06

US3162037

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:27:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '05 Aug 2020 12:00'	System	31 Jul 2020 22:07:27

**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '06 Aug 2020 11:59'	System	31 Jul 2020 22:07:27

**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	31 Jul 2020 22:07:27
User entered 'Day 7'	System	31 Jul 2020 22:07:27

US3162037

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:27:33

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-06T20:44:02', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'd7795bb8-6b4e-4ffc-a142-06100cb4ccd4'	System	07 Aug 2020 03:44:38
User entered 'No interference with activity (1)'	System	07 Aug 2020 03:44:38

**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:27:33**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-06T20:44:08', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'd7795bb8-6b4e-4ffc-a142-06100cb4ccd4'	System	07 Aug 2020 03:44:38
User entered 'No interference with activity (1)'	System	07 Aug 2020 03:44:38



US3162037

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:27:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-06T20:44:15', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'd7795bb8-6b4e-4ffc-a142-06100cb4ccd4'	System	07 Aug 2020 03:44:38
User entered 'No interference with activity (1)'	System	07 Aug 2020 03:44:38

US3162037

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:27:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-06T20:44:21', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'd7795bb8-6b4e-4ffc-a142-06100cb4ccd4'	System	07 Aug 2020 03:44:38
User entered 'No interference with activity (1)'	System	07 Aug 2020 03:44:38

**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:27:33**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-06T20:44:27', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'd7795bb8-6b4e-4ffc-a142-06100cb4ccd4' User entered 'None (0)'	System	07 Aug 2020 03:44:38
	System	07 Aug 2020 03:44:38

**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:27:33**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-06T20:44:30', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'd7795bb8-6b4e-4ffc-a142-06100cb4ccd4' User entered 'None (0)'	System	07 Aug 2020 03:44:38
	System	07 Aug 2020 03:44:38

US3162037

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:27:33

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)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-06T20:44:33', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'd7795bb8-6b4e-4ffc-a142-06100cb4ccd4' User entered 'No (N)'	System	07 Aug 2020 03:44:38
	System	07 Aug 2020 03:44:38

**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-06T20:44:36', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'd7795bb8-6b4e-4ffc-a142-06100cb4ccd4' User entered '06 Aug 2020 20:44'	System	07 Aug 2020 03:44:38
	System	07 Aug 2020 03:44:38

US3162037

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:27:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '06 Aug 2020 12:00'	System	31 Jul 2020 22:07:27

US3162037

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:27:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '07 Aug 2020 11:59'	System	31 Jul 2020 22:07:27



US3162037

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	07 Aug 2020 03:44:38
User entered 'Day 8'	System	07 Aug 2020 03:44:38

**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(8)**

**Generated On: 09 Jun 2021 15:27:33**

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-07T20:26:41', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'ed2fe131-2bda-4eb3-b88b-1ea2c6545f9c' User entered 'None (0)'	System	08 Aug 2020 03:26:46
	System	08 Aug 2020 03:26:46

**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(8)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-07T20:26:44', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'ed2fe131-2bda-4eb3-b88b-1ea2c6545f9c' User entered '07 Aug 2020 20:26'	System	08 Aug 2020 03:26:46
	System	08 Aug 2020 03:26:46

**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(8)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '07 Aug 2020 12:00'	System	07 Aug 2020 03:44:38

**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(8)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 03:44:38

US3162037

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	07 Aug 2020 03:44:38
User entered 'Day 8'	System	07 Aug 2020 03:44:38

**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 09 Jun 2021 15:27:33**

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-07T20:26:30', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'b8690481-fd80-49a9-89db-67dbf8be2333' User entered 'None (0)'	System	08 Aug 2020 03:26:37
	System	08 Aug 2020 03:26:37

**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-07T20:26:35', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'b8690481-fd80-49a9-89db-67dbf8be2333'	System	08 Aug 2020 03:26:37
User entered '07 Aug 2020 20:26'	System	08 Aug 2020 03:26:37



US3162037

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 09 Jun 2021 15:27:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '07 Aug 2020 12:00'	System	07 Aug 2020 03:44:38

US3162037

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 09 Jun 2021 15:27:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 03:44:38

**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(8)**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	06 Aug 2020 03:51:06
User entered 'Day 8'	System	06 Aug 2020 03:51:06

US3162037

Folder: Diary Dose 1 (1)

Form: MuscleAche\_Day(8)

Generated On: 09 Jun 2021 15:27:33

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-07T20:26:21', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '2cafb7cc-6b66-411f-aa28-28bd2fddee54' User entered 'None (0)'	System	08 Aug 2020 03:26:29
	System	08 Aug 2020 03:26:29

**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(8)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-07T20:26:24', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '2cafb7cc-6b66-411f-aa28-28bd2fddee54' User entered '07 Aug 2020 20:26'	System	08 Aug 2020 03:26:29
	System	08 Aug 2020 03:26:29

**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(8)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 03:51:06

**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: MuscleAche\_Day(8)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 03:51:06

US3162037

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(8)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	06 Aug 2020 03:51:06
User entered 'Day 8'	System	06 Aug 2020 03:51:06



**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(8)**

**Generated On: 09 Jun 2021 15:27:33**

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-07T20:26:10', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '7fa1360b-fa13-481d-bdf8-c2796c4f4f25' User entered 'None (0)'	System	08 Aug 2020 03:26:19
	System	08 Aug 2020 03:26:19

**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(8)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-07T20:26:13', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '7fa1360b-fa13-481d-bdf8-c2796c4f4f25' User entered '07 Aug 2020 20:26'	System	08 Aug 2020 03:26:19
	System	08 Aug 2020 03:26:19

**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(8)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 03:51:06

**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: JointsAche\_Day(8)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 03:51:06

US3162037

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	06 Aug 2020 03:51:06
User entered 'Day 8'	System	06 Aug 2020 03:51:06

US3162037

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 15:27:33

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)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-07T20:25:57', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'e2a750f3-b5c1-47b7-b0b4-343455dbf4b9'	System	08 Aug 2020 03:26:07
User entered 'No (N)'	System	08 Aug 2020 03:26:07

**US3162037**

**Folder: Diary Dose 1 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-07T20:26:03', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'e2a750f3-b5c1-47b7-b0b4-343455dbf4b9' User entered '07 Aug 2020 20:26'	System	08 Aug 2020 03:26:07
	System	08 Aug 2020 03:26:07

US3162037

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 15:27:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 03:51:06



US3162037

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 15:27:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 03:51:06

**US3162037**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:27:33**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	22 Aug 2020 02:14:47

US3162037

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '7 Aug 2020'	Jared Bradshaw (b) (4) (b) (4)	22 Aug 2020 02:14:47

**US3162037**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:27:33**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'Contact Made (CONTACT MADE)'	Jared Bradshaw (b) (4) (b) (4)	22 Aug 2020 02:14:47

US3162037

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:27:33

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	22 Aug 2020 02:14:47

US3162037

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:27:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	22 Aug 2020 02:14:51

**US3162037**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:27:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User entered 'I'	System	22 Aug 2020 02:14:51

**US3162037**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:27:33**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	22 Aug 2020 02:15:11



US3162037

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4)	13 Feb 2021 01:34:22
	(b) (4)	
User entered '15 Aug 2020'	Jared Bradshaw (b) (4)	22 Aug 2020 02:15:11
	(b) (4)	

**US3162037**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:27:33**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'Contact Made (CONTACT MADE)'	Jared Bradshaw (b) (4) (b) (4)	22 Aug 2020 02:15:11

US3162037

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:27:33

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	22 Aug 2020 02:15:11

US3162037

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:27:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	22 Aug 2020 02:15:16

**US3162037**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:27:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User entered 'I'	System	22 Aug 2020 02:15:16

**US3162037**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:27:33**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	22 Aug 2020 02:17:00

US3162037

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4)	13 Feb 2021 01:34:22
	(b) (4)	
User entered '21 Aug 2020'	Jared Bradshaw (b) (4)	22 Aug 2020 02:17:00
	(b) (4)	

US3162037

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:27:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'Contact Made (CONTACT MADE)'	Jared Bradshaw (b) (4) (b) (4)	22 Aug 2020 02:17:00



US3162037

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:27:33

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	22 Aug 2020 02:17:00

US3162037

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:27:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	22 Aug 2020 02:17:06

**US3162037**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:27:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User entered 'I'	System	22 Aug 2020 02:17:06

**US3162037**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:27:33**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 20:53:05

US3162037

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:27:33

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '28 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 20:53:05

US3162037

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:27:33

[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 04:04:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	28 Aug 2020 20:53:05

**US3162037**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:27:33**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User entered 'VISIT2'	System	28 Aug 2020 20:53:05

US3162037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	28 Aug 2020 20:57:33



US3162037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 20:57:33

US3162037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '28 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 20:57:33

US3162037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '12:29'	(b) (4), (b) (6)	28 Aug 2020 20:57:33

**US3162037**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:27:33**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User entered '28 Aug 2020 12:29'	System	28 Aug 2020 20:57:33

US3162037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '98.1' F	(b) (4), (b) (6)	28 Aug 2020 20:57:33

US3162037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'Oral (Oral)'	(b) (4), (b) (6)	28 Aug 2020 20:57:33

US3162037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 20:57:33

US3162037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '73'	(b) (4), (b) (6)	28 Aug 2020 20:57:33



US3162037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User entered 'bpm'	System	28 Aug 2020 20:57:33

US3162037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '15'	(b) (4), (b) (6)	28 Aug 2020 20:57:33

US3162037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User entered 'breaths/min'	System	28 Aug 2020 20:57:33

US3162037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '121'	(b) (4), (b) (6)	28 Aug 2020 20:57:33

US3162037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User entered 'mmHg'	System	28 Aug 2020 20:57:33

US3162037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '81'	(b) (4), (b) (6)	28 Aug 2020 20:57:33

US3162037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User entered 'mmHg'	System	28 Aug 2020 20:57:33

US3162037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	28 Aug 2020 20:57:33



US3162037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 00:09:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 00:09:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Jourdan Manfred (b) (4) (b) (4)	03 Sep 2020 00:09:26
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 20:57:33
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 20:57:33

US3162037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '28 Aug 2020' reason for change: Data Entry Error	Jourdan Manfred (b) (4) (b) (4)	03 Sep 2020 00:09:26
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 20:57:33

US3162037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User signature succeeded.	Judith Kirstein (b) (4)	13 Feb 2021 01:35:19
	(b) (4)	
User entered '14:25' reason for change: Data Entry Error	Jourdan Manfred (b) (4)	03 Sep 2020 00:09:26
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 20:57:33

US3162037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User entered '28 Aug 2020 14:25'	System	03 Sep 2020 00:09:26
User entered empty.	System	28 Aug 2020 20:57:33

US3162037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '97.6' F reason for change: Data Entry Error	Jourdan Manfred (b) (4) (b) (4)	03 Sep 2020 00:09:26
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 20:57:33

US3162037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User signature succeeded.	Judith Kirstein (b) (4)	13 Feb 2021 01:35:19
	(b) (4)	
User entered 'Oral (Oral)' reason for change: Data Entry Error	Jourdan Manfred (b) (4)	03 Sep 2020 00:09:26
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	28 Aug 2020 20:57:33

US3162037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 20:57:33

US3162037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '68' reason for change: Data Entry Error	Jourdan Manfred (b) (4) (b) (4)	03 Sep 2020 00:09:26
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 20:57:33



US3162037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User entered 'bpm'	System	03 Sep 2020 00:09:26
User entered empty.	System	28 Aug 2020 20:57:33

US3162037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '15' reason for change: Data Entry Error	Jourdan Manfred (b) (4) (b) (4)	03 Sep 2020 00:09:26
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 20:57:33

US3162037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User entered 'breaths/min'	System	03 Sep 2020 00:09:26
User entered empty.	System	28 Aug 2020 20:57:33

US3162037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User signature succeeded.	Judith Kirstein (b) (4)	13 Feb 2021 01:35:19
	(b) (4)	
User entered '131' reason for change: Data Entry Error	Jourdan Manfred (b) (4)	03 Sep 2020 00:09:26
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 20:57:33

US3162037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User entered 'mmHg'	System	03 Sep 2020 00:09:26
User entered empty.	System	28 Aug 2020 20:57:33

US3162037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '79' reason for change: Data Entry Error	Jourdan Manfred (b) (4) (b) (4)	03 Sep 2020 00:09:26
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 20:57:33

US3162037

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User entered 'mmHg'	System	03 Sep 2020 00:09:26
User entered empty.	System	28 Aug 2020 20:57:33

US3162037

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:27:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 20:57:46



US3162037

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:27:33

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '28 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 20:57:46

US3162037

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:27:33

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 20:58:14

US3162037

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:27:33

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 20:58:14

US3162037

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:27:33

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 04:04:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 20:58:14

US3162037

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:27:33

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User entered 'MRNA-1273 OR PLACEBO'	System	28 Aug 2020 20:58:14

US3162037

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:27:33

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '28 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 20:58:14

US3162037

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:27:33

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '13:44'	(b) (4), (b) (6)	28 Aug 2020 20:58:14

US3162037

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:27:33

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User entered '28 Aug 2020 13:44'	System	28 Aug 2020 20:58:14



US3162037

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:27:33

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User closed query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	(b) (4), (b) (6)	11 Sep 2020 02:15:17
Query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' answered with 'Per PI: Because of the recent onset of pain in left shoulder, PI directed the vaccine to be given in right arm.' (Site from System).	Cynthia Kunakom (b) (4) (b) (4)	08 Sep 2020 20:34:24
User opened query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	System	28 Aug 2020 20:58:14
User entered 'Right Arm (RIGHT ARM)'	(b) (4), (b) (6)	28 Aug 2020 20:58:14

US3162037

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:27:33

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User entered 'ONCE'	System	28 Aug 2020 20:58:14

US3162037

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:27:33

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User entered 'INTRAMUSCULAR'	System	28 Aug 2020 20:58:14

US3162037

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:27:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 20:12:34

US3162037

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:27:33

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '28 Aug 2020'	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 20:12:34

US3162037

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:27:33

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '13:17'	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 20:12:34

**US3162037**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:27:33**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User entered '28 Aug 2020 13:17'	System	01 Sep 2020 20:12:34

US3162037

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:27:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '28 Aug 2020'	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 20:12:44



**US3162037**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:27:33**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Cynthia Kunakom (b) (4)	01 Sep 2020 20:12:44

US3162037

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:27:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 20:12:44

US3162037

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:27:33

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '13:21'	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 20:12:44

**US3162037**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:27:33**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User entered '28 Aug 2020 13:21'	System	01 Sep 2020 20:12:44

**US3162037**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:27:33**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Cynthia Kunakom (b) (4)	01 Sep 2020 20:12:44

US3162037

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:27:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 20:12:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Sep 2020 20:12:52
User entered 'No (N)' reason for change: Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 20:12:52
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 20:12:44
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 20:12:44

**US3162037**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:27:33**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 20:12:44

**US3162037**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:27:33**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User entered empty.	System	01 Sep 2020 20:12:44



US3162037

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:27:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 21:20:55

**US3162037**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:27:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User entered '1'	System	28 Aug 2020 21:20:55

US3162037

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	28 Aug 2020 20:58:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 20:58:14

US3162037

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-28T14:10:43', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '049408b8-604f-419d-a4ff-3d2dd56f2f45'	System	28 Aug 2020 21:11:06
User entered 'Yes (Y)'	System	28 Aug 2020 21:11:06

US3162037

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-28T14:10:50', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '049408b8-604f-419d-a4ff-3d2dd56f2f45'	System	28 Aug 2020 21:11:06
User entered '97.6'	System	28 Aug 2020 21:11:06

US3162037

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-28T14:10:55', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '049408b8-604f-419d-a4ff-3d2dd56f2f45'	System	28 Aug 2020 21:11:06
User entered 'No (N)'	System	28 Aug 2020 21:11:06

**US3162037**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-28T14:11:03', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '049408b8-604f-419d-a4ff-3d2dd56f2f45'	System	28 Aug 2020 21:11:06
User entered '28 Aug 2020 14:11'	System	28 Aug 2020 21:11:06

US3162037

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '28 Aug 2020 14:04'	System	28 Aug 2020 20:58:14



US3162037

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '28 Aug 2020 16:34'	System	28 Aug 2020 20:58:14

US3162037

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	28 Aug 2020 20:58:14
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 20:58:14

US3162037

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-28T21:37:46', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '8f495127-ae1b-4c40-bfa5-2ff247ae8418' User entered 'Yes (Y)'	System	29 Aug 2020 04:38:10
	System	29 Aug 2020 04:38:10

US3162037

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-28T21:37:56', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '8f495127-ae1b-4c40-bfa5-2ff247ae8418' User entered '97.6'	System	29 Aug 2020 04:38:10
	System	29 Aug 2020 04:38:10

US3162037

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-28T21:38:01', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '8f495127-ae1b-4c40-bfa5-2ff247ae8418'	System	29 Aug 2020 04:38:10
User entered 'No (N)'	System	29 Aug 2020 04:38:10

**US3162037**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-28T21:38:05', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '8f495127-ae1b-4c40-bfa5-2ff247ae8418' User entered '28 Aug 2020 21:38'	System	29 Aug 2020 04:38:10
	System	29 Aug 2020 04:38:10

US3162037

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '28 Aug 2020 17:29'	System	28 Aug 2020 20:58:14

US3162037

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 20:58:14



US3162037

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	28 Aug 2020 20:58:14
User entered 'Day 2'	System	28 Aug 2020 20:58:14

US3162037

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:27:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-29T20:00:25', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '352c7cfc-fa70-4c72-8f9b-25d9e0d3ebb6' User entered 'Yes (Y)'	System	30 Aug 2020 03:00:43
	System	30 Aug 2020 03:00:43

US3162037

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:27:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-29T20:00:33', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '352c7cfc-fa70-4c72-8f9b-25d9e0d3ebb6' User entered '96.8'	System	30 Aug 2020 03:00:43
	System	30 Aug 2020 03:00:43

US3162037

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-29T20:00:37', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '352c7cfc-fa70-4c72-8f9b-25d9e0d3ebb6'	System	30 Aug 2020 03:00:43
User entered 'No (N)'	System	30 Aug 2020 03:00:43

**US3162037**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-29T20:00:41', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '352c7cfc-fa70-4c72-8f9b-25d9e0d3ebb6'	System	30 Aug 2020 03:00:43
User entered '29 Aug 2020 20:00'	System	30 Aug 2020 03:00:43

US3162037

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:27:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 20:58:14

US3162037

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:27:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 20:58:14

US3162037

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	28 Aug 2020 20:58:14
User entered 'Day 3'	System	28 Aug 2020 20:58:14



US3162037

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:27:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-30T17:28:57', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '1b416e53-722b-4b75-96c8-8fe2bd87c20f' User entered 'Yes (Y)'	System	31 Aug 2020 00:30:17
	System	31 Aug 2020 00:30:17

US3162037

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:27:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-30T17:29:09', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '1b416e53-722b-4b75-96c8-8fe2bd87c20f' User entered '97.1'	System	31 Aug 2020 00:30:17
	System	31 Aug 2020 00:30:17

US3162037

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-30T17:29:12', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '1b416e53-722b-4b75-96c8-8fe2bd87c20f' User entered 'No (N)'	System	31 Aug 2020 00:30:17
	System	31 Aug 2020 00:30:17

**US3162037**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-30T17:29:16', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '1b416e53-722b-4b75-96c8-8fe2bd87c20f' User entered '30 Aug 2020 17:29'	System	31 Aug 2020 00:30:17
	System	31 Aug 2020 00:30:17

US3162037

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:27:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 20:58:14

US3162037

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:27:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 20:58:14

US3162037

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	28 Aug 2020 20:58:14
User entered 'Day 4'	System	28 Aug 2020 20:58:14

US3162037

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:27:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-31T20:23:16', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '4426f2d6-64c1-40b1-adce-28e215a6f4f4' User entered 'Yes (Y)'	System	01 Sep 2020 03:23:35
	System	01 Sep 2020 03:23:35



US3162037

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:27:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-31T20:23:25', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '4426f2d6-64c1-40b1-adce-28e215a6f4f4' User entered '96.0'	System	01 Sep 2020 03:23:35
	System	01 Sep 2020 03:23:35

US3162037

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-31T20:23:29', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '4426f2d6-64c1-40b1-adce-28e215a6f4f4'	System	01 Sep 2020 03:23:35
User entered 'No (N)'	System	01 Sep 2020 03:23:35

**US3162037**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-31T20:23:32', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '4426f2d6-64c1-40b1-adce-28e215a6f4f4'	System	01 Sep 2020 03:23:35
User entered '31 Aug 2020 20:23'	System	01 Sep 2020 03:23:35

**US3162037**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 20:58:14

US3162037

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:27:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 20:58:14

US3162037

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	28 Aug 2020 20:58:14
User entered 'Day 5'	System	28 Aug 2020 20:58:14

US3162037

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:27:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-09-01T19:26:24', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'c1f753d7-8bbd-47f3-ab38-593e825a5a45'	System	02 Sep 2020 02:26:53
User entered 'Yes (Y)'	System	02 Sep 2020 02:26:53

US3162037

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:27:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-09-01T19:26:39', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'c1f753d7-8bbd-47f3-ab38-593e825a5a45' User entered '96.1'	System	02 Sep 2020 02:26:53
	System	02 Sep 2020 02:26:53



US3162037

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-09-01T19:26:48', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'c1f753d7-8bbd-47f3-ab38-593e825a5a45'	System	02 Sep 2020 02:26:53
User entered 'No (N)'	System	02 Sep 2020 02:26:53

**US3162037**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-09-01T19:26:51', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'c1f753d7-8bbd-47f3-ab38-593e825a5a45'	System	02 Sep 2020 02:26:53
User entered '01 Sep 2020 19:26'	System	02 Sep 2020 02:26:53

US3162037

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:27:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 20:58:14

US3162037

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:27:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 20:58:14

US3162037

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	28 Aug 2020 20:58:14
User entered 'Day 6'	System	28 Aug 2020 20:58:14

US3162037

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:27:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-09-02T22:22:41', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '388441ec-c42e-4a25-8a06-5b2f9b93333d' User entered 'Yes (Y)'	System	03 Sep 2020 05:22:55
	System	03 Sep 2020 05:22:55

US3162037

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:27:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-09-02T22:22:47', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '388441ec-c42e-4a25-8a06-5b2f9b93333d' User entered '96.6'	System	03 Sep 2020 05:22:55
	System	03 Sep 2020 05:22:55

US3162037

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-09-02T22:22:51', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '388441ec-c42e-4a25-8a06-5b2f9b93333d' User entered 'No (N)'	System	03 Sep 2020 05:22:55
	System	03 Sep 2020 05:22:55



**US3162037**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-09-02T22:22:54', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '388441ec-c42e-4a25-8a06-5b2f9b93333d' User entered '02 Sep 2020 22:22'	System	03 Sep 2020 05:22:55
	System	03 Sep 2020 05:22:55

US3162037

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:27:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 20:58:14

US3162037

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:27:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 20:58:14

US3162037

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	28 Aug 2020 20:58:14
User entered 'Day 7'	System	28 Aug 2020 20:58:14

US3162037

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:27:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-09-03T17:09:53', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '20f2c852-e333-4325-9691-d1f05adaa891'	System	04 Sep 2020 00:10:48
User entered 'Yes (Y)'	System	04 Sep 2020 00:10:48

US3162037

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:27:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-09-03T17:10:40', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '20f2c852-e333-4325-9691-d1f05adaa891' User entered '95.7'	System	04 Sep 2020 00:10:48
	System	04 Sep 2020 00:10:48

US3162037

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-09-03T17:10:43', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '20f2c852-e333-4325-9691-d1f05adaa891'	System	04 Sep 2020 00:10:48
User entered 'No (N)'	System	04 Sep 2020 00:10:48

**US3162037**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-09-03T17:10:45', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '20f2c852-e333-4325-9691-d1f05adaa891' User entered '03 Sep 2020 17:10'	System	04 Sep 2020 00:10:48
	System	04 Sep 2020 00:10:48



US3162037

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:27:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 20:58:14

US3162037

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:27:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 20:58:14

US3162037

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	28 Aug 2020 20:58:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 20:58:14

US3162037

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-28T14:11:12', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '4acf5527-9e33-4597-8d8e-bcbb60865313'	System	28 Aug 2020 21:11:35
User entered 'None (1)'	System	28 Aug 2020 21:11:35

US3162037

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-28T14:11:22', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '4acf5527-9e33-4597-8d8e-bcbb60865313'	System	28 Aug 2020 21:11:35
User entered 'No (N)'	System	28 Aug 2020 21:11:35

US3162037

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-28T14:11:25', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '4acf5527-9e33-4597-8d8e-bcbb60865313' User entered 'No (N)'	System	28 Aug 2020 21:11:35
	System	28 Aug 2020 21:11:35

US3162037

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-28T14:11:28', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '4acf5527-9e33-4597-8d8e-bcbb60865313'	System	28 Aug 2020 21:11:35
User entered 'None (1)'	System	28 Aug 2020 21:11:35

**US3162037**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-28T14:11:32', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '4acf5527-9e33-4597-8d8e-bcbb60865313' User entered '28 Aug 2020 14:11'	System	28 Aug 2020 21:11:35
	System	28 Aug 2020 21:11:35



US3162037

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '28 Aug 2020 14:04'	System	28 Aug 2020 20:58:14

**US3162037**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '28 Aug 2020 16:34'	System	28 Aug 2020 20:58:14

US3162037

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	28 Aug 2020 20:58:14
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 20:58:14

US3162037

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-28T21:38:12', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'aa8d68d7-3b68-4eb0-bd2d-6f914a01d36c' User entered 'None (1)'	System	29 Aug 2020 04:38:38
	System	29 Aug 2020 04:38:38

US3162037

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-28T21:38:19', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'aa8d68d7-3b68-4eb0-bd2d-6f914a01d36c' User entered 'No (N)'	System	29 Aug 2020 04:38:38
	System	29 Aug 2020 04:38:38

US3162037

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-28T21:38:26', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'aa8d68d7-3b68-4eb0-bd2d-6f914a01d36c' User entered 'No (N)'	System	29 Aug 2020 04:38:38
	System	29 Aug 2020 04:38:38

US3162037

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-28T21:38:31', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'aa8d68d7-3b68-4eb0-bd2d-6f914a01d36c' User entered 'None (1)'	System	29 Aug 2020 04:38:38
	System	29 Aug 2020 04:38:38

**US3162037**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-28T21:38:35', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'aa8d68d7-3b68-4eb0-bd2d-6f914a01d36c' User entered '28 Aug 2020 21:38'	System	29 Aug 2020 04:38:38
	System	29 Aug 2020 04:38:38



US3162037

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '28 Aug 2020 17:29'	System	28 Aug 2020 20:58:14

US3162037

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 20:58:14

US3162037

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	28 Aug 2020 20:58:14
User entered 'Day 2'	System	28 Aug 2020 20:58:14

US3162037

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:27:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-29T20:00:04', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '4adfb9ff-6a81-429a-845c-e5250b95ba5f'	System	30 Aug 2020 03:00:22
User entered 'None (1)'	System	30 Aug 2020 03:00:22

US3162037

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:27:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-29T20:00:08', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '4adfb9ff-6a81-429a-845c-e5250b95ba5f' User entered 'No (N)'	System	30 Aug 2020 03:00:22
	System	30 Aug 2020 03:00:22

US3162037

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-29T20:00:12', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '4adfb9ff-6a81-429a-845c-e5250b95ba5f' User entered 'No (N)'	System	30 Aug 2020 03:00:22
	System	30 Aug 2020 03:00:22

US3162037

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:27:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-29T20:00:15', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '4adfb9ff-6a81-429a-845c-e5250b95ba5f'	System	30 Aug 2020 03:00:22
User entered 'None (1)'	System	30 Aug 2020 03:00:22

**US3162037**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-29T20:00:18', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '4adfb9ff-6a81-429a-845c-e5250b95ba5f' User entered '29 Aug 2020 20:00'	System	30 Aug 2020 03:00:22
	System	30 Aug 2020 03:00:22



US3162037

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:27:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 20:58:14

**US3162037**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 20:58:14

US3162037

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	28 Aug 2020 20:58:14
User entered 'Day 3'	System	28 Aug 2020 20:58:14

US3162037

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:27:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-30T17:28:38', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'eee083b3-6e1b-450b-9cd7-02d198a1a3c4'	System	31 Aug 2020 00:29:55
User entered 'None (1)'	System	31 Aug 2020 00:29:55

US3162037

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:27:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-30T17:28:41', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'eee083b3-6e1b-450b-9cd7-02d198a1a3c4'	System	31 Aug 2020 00:29:55
User entered 'No (N)'	System	31 Aug 2020 00:29:55

US3162037

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-30T17:28:44', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'eee083b3-6e1b-450b-9cd7-02d198a1a3c4'	System	31 Aug 2020 00:29:55
User entered 'No (N)'	System	31 Aug 2020 00:29:55

US3162037

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:27:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-30T17:28:47', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'eee083b3-6e1b-450b-9cd7-02d198a1a3c4' User entered 'None (1)'	System	31 Aug 2020 00:29:55
	System	31 Aug 2020 00:29:55

**US3162037**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-30T17:28:50', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'eee083b3-6e1b-450b-9cd7-02d198a1a3c4'	System	31 Aug 2020 00:29:55
User entered '30 Aug 2020 17:28'	System	31 Aug 2020 00:29:55



US3162037

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:27:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 20:58:14

**US3162037**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 20:58:14

US3162037

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	28 Aug 2020 20:58:14
User entered 'Day 4'	System	28 Aug 2020 20:58:14

US3162037

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:27:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-31T20:22:47', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'd8cea3ed-368e-4012-a719-61b4f8fed0a5'	System	01 Sep 2020 03:23:04
User entered 'None (1)'	System	01 Sep 2020 03:23:04

US3162037

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:27:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-31T20:22:51', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'd8cea3ed-368e-4012-a719-61b4f8fed0a5'	System	01 Sep 2020 03:23:04
User entered 'No (N)'	System	01 Sep 2020 03:23:04

US3162037

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-31T20:22:54', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'd8cea3ed-368e-4012-a719-61b4f8fed0a5'	System	01 Sep 2020 03:23:04
User entered 'No (N)'	System	01 Sep 2020 03:23:04

US3162037

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:27:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-31T20:22:59', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'd8cea3ed-368e-4012-a719-61b4f8fed0a5'	System	01 Sep 2020 03:23:04
User entered 'None (1)'	System	01 Sep 2020 03:23:04

**US3162037**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-31T20:23:02', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'd8cea3ed-368e-4012-a719-61b4f8fed0a5'	System	01 Sep 2020 03:23:04
User entered '31 Aug 2020 20:23'	System	01 Sep 2020 03:23:04



US3162037

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:27:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 20:58:14

**US3162037**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 20:58:14

US3162037

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	28 Aug 2020 20:58:14
User entered 'Day 5'	System	28 Aug 2020 20:58:14

US3162037

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:27:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-09-01T19:26:06', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '9e3c3025-2625-4bc4-8656-f09c1d6b8e19'	System	02 Sep 2020 02:26:21
User entered 'None (1)'	System	02 Sep 2020 02:26:21

US3162037

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:27:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-09-01T19:26:09', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '9e3c3025-2625-4bc4-8656-f09c1d6b8e19' User entered 'No (N)'	System	02 Sep 2020 02:26:21
	System	02 Sep 2020 02:26:21

US3162037

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-09-01T19:26:12', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '9e3c3025-2625-4bc4-8656-f09c1d6b8e19' User entered 'No (N)'	System	02 Sep 2020 02:26:21
	System	02 Sep 2020 02:26:21

US3162037

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:27:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-09-01T19:26:15', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '9e3c3025-2625-4bc4-8656-f09c1d6b8e19'	System	02 Sep 2020 02:26:21
User entered 'None (1)'	System	02 Sep 2020 02:26:21

**US3162037**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-09-01T19:26:18', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '9e3c3025-2625-4bc4-8656-f09c1d6b8e19' User entered '01 Sep 2020 19:26'	System	02 Sep 2020 02:26:21
	System	02 Sep 2020 02:26:21



US3162037

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:27:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 20:58:14

US3162037

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:27:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 20:58:14

US3162037

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	28 Aug 2020 20:58:14
User entered 'Day 6'	System	28 Aug 2020 20:58:14

US3162037

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:27:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-09-02T22:22:16', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'ff1fb63b-ee7a-4cea-9d4e-30e4c2c06784' User entered 'None (1)'	System	03 Sep 2020 05:22:29
	System	03 Sep 2020 05:22:29

US3162037

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:27:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-09-02T22:22:19', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'ff1fb63b-ee7a-4cea-9d4e-30e4c2c06784' User entered 'No (N)'	System	03 Sep 2020 05:22:29
	System	03 Sep 2020 05:22:29

US3162037

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-09-02T22:22:21', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'ff1fb63b-ee7a-4cea-9d4e-30e4c2c06784' User entered 'No (N)'	System	03 Sep 2020 05:22:29
	System	03 Sep 2020 05:22:29

US3162037

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:27:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-09-02T22:22:24', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'ff1fb63b-ee7a-4cea-9d4e-30e4c2c06784' User entered 'None (1)'	System	03 Sep 2020 05:22:29
	System	03 Sep 2020 05:22:29

**US3162037**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-09-02T22:22:27', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'ff1fb63b-ee7a-4cea-9d4e-30e4c2c06784' User entered '02 Sep 2020 22:22'	System	03 Sep 2020 05:22:29
	System	03 Sep 2020 05:22:29



US3162037

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:27:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 20:58:14

US3162037

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:27:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 20:58:14

US3162037

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	28 Aug 2020 20:58:14
User entered 'Day 7'	System	28 Aug 2020 20:58:14

US3162037

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:27:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-09-03T17:09:36', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '2343eceb-2e82-4bc3-9d6d-3dda06e58695'	System	04 Sep 2020 00:09:50
User entered 'None (1)'	System	04 Sep 2020 00:09:50

US3162037

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:27:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-09-03T17:09:39', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '2343eceb-2e82-4bc3-9d6d-3dda06e58695' User entered 'No (N)'	System	04 Sep 2020 00:09:50
	System	04 Sep 2020 00:09:50

US3162037

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-09-03T17:09:42', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '2343eceb-2e82-4bc3-9d6d-3dda06e58695' User entered 'No (N)'	System	04 Sep 2020 00:09:50
	System	04 Sep 2020 00:09:50

US3162037

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:27:33

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-09-03T17:09:44', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '2343eceb-2e82-4bc3-9d6d-3dda06e58695'	System	04 Sep 2020 00:09:50
User entered 'None (1)'	System	04 Sep 2020 00:09:50

**US3162037**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-09-03T17:09:47', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '2343eceb-2e82-4bc3-9d6d-3dda06e58695' User entered '03 Sep 2020 17:09'	System	04 Sep 2020 00:09:50
	System	04 Sep 2020 00:09:50



US3162037

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:27:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 20:58:14

**US3162037**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 20:58:14

US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	28 Aug 2020 20:58:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 20:58:14

**US3162037**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:27:33**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-28T14:11:37', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '6753a694-cdf5-4216-89c0-c4479c0fb77e' User entered 'None (0)'	System	28 Aug 2020 21:12:08
	System	28 Aug 2020 21:12:08

US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-28T14:11:40', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '6753a694-cdf5-4216-89c0-c4479c0fb77e' User entered 'None (0)'	System	28 Aug 2020 21:12:08
	System	28 Aug 2020 21:12:08

US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-28T14:11:45', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '6753a694-cdf5-4216-89c0-c4479c0fb77e' User entered 'None (0)'	System	28 Aug 2020 21:12:08
	System	28 Aug 2020 21:12:08

US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-28T14:11:50', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '6753a694-cdf5-4216-89c0-c4479c0fb77e' User entered 'None (0)'	System	28 Aug 2020 21:12:08
	System	28 Aug 2020 21:12:08

**US3162037**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:27:33**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-28T14:11:53', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '6753a694-cdf5-4216-89c0-c4479c0fb77e' User entered 'None (0)'	System	28 Aug 2020 21:12:08
	System	28 Aug 2020 21:12:08



**US3162037**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:27:33**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-28T14:11:56', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '6753a694-cdf5-4216-89c0-c4479c0fb77e' User entered 'None (0)'	System	28 Aug 2020 21:12:08
	System	28 Aug 2020 21:12:08

US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

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)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-28T14:12:01', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '6753a694-cdf5-4216-89c0-c4479c0fb77e' User entered 'No (N)'	System	28 Aug 2020 21:12:08
	System	28 Aug 2020 21:12:08

**US3162037**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-28T14:12:04', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '6753a694-cdf5-4216-89c0-c4479c0fb77e' User entered '28 Aug 2020 14:12'	System	28 Aug 2020 21:12:08
	System	28 Aug 2020 21:12:08

US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:27:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '28 Aug 2020 14:04'	System	28 Aug 2020 20:58:14

**US3162037**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '28 Aug 2020 16:34'	System	28 Aug 2020 20:58:14

US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	28 Aug 2020 20:58:14
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 20:58:14

**US3162037**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:27:33**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-28T21:38:41', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '85c7e78d-9b8f-4df3-84a4-5c22570905f0' User entered 'None (0)'	System	29 Aug 2020 04:39:07
	System	29 Aug 2020 04:39:07

US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-28T21:38:45', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '85c7e78d-9b8f-4df3-84a4-5c22570905f0' User entered 'None (0)'	System	29 Aug 2020 04:39:07
	System	29 Aug 2020 04:39:07



US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-28T21:38:49', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '85c7e78d-9b8f-4df3-84a4-5c22570905f0' User entered 'None (0)'	System	29 Aug 2020 04:39:07
	System	29 Aug 2020 04:39:07

US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-28T21:38:53', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '85c7e78d-9b8f-4df3-84a4-5c22570905f0' User entered 'None (0)'	System	29 Aug 2020 04:39:07
	System	29 Aug 2020 04:39:07

**US3162037**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:27:33**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-28T21:38:56', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '85c7e78d-9b8f-4df3-84a4-5c22570905f0' User entered 'None (0)'	System	29 Aug 2020 04:39:07
	System	29 Aug 2020 04:39:07

US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-28T21:38:59', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '85c7e78d-9b8f-4df3-84a4-5c22570905f0' User entered 'None (0)'	System	29 Aug 2020 04:39:07
	System	29 Aug 2020 04:39:07

US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

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)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-28T21:39:03', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '85c7e78d-9b8f-4df3-84a4-5c22570905f0' User entered 'No (N)'	System	29 Aug 2020 04:39:07
	System	29 Aug 2020 04:39:07

**US3162037**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-28T21:39:06', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '85c7e78d-9b8f-4df3-84a4-5c22570905f0' User entered '28 Aug 2020 21:39'	System	29 Aug 2020 04:39:07
	System	29 Aug 2020 04:39:07

US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:27:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '28 Aug 2020 17:29'	System	28 Aug 2020 20:58:14

**US3162037**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 20:58:14



US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	28 Aug 2020 20:58:14
User entered 'Day 2'	System	28 Aug 2020 20:58:14

**US3162037**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:27:33**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-29T19:59:05', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '1c1b81dc-00b0-4574-90b5-955acfc37d5a' User entered 'None (0)'	System	30 Aug 2020 02:59:35
	System	30 Aug 2020 02:59:35

**US3162037**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:27:33**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-29T19:59:10', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '1c1b81dc-00b0-4574-90b5-955acfc37d5a' User entered 'None (0)'	System	30 Aug 2020 02:59:35
	System	30 Aug 2020 02:59:35

US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:27:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-29T19:59:13', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '1c1b81dc-00b0-4574-90b5-955acfc37d5a' User entered 'None (0)'	System	30 Aug 2020 02:59:35
	System	30 Aug 2020 02:59:35

US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:27:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-29T19:59:17', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '1c1b81dc-00b0-4574-90b5-955acfc37d5a' User entered 'None (0)'	System	30 Aug 2020 02:59:35
	System	30 Aug 2020 02:59:35

**US3162037**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:27:33**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-29T19:59:20', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '1c1b81dc-00b0-4574-90b5-955acfc37d5a' User entered 'None (0)'	System	30 Aug 2020 02:59:35
	System	30 Aug 2020 02:59:35

**US3162037**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:27:33**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-29T19:59:25', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '1c1b81dc-00b0-4574-90b5-955acfc37d5a' User entered 'None (0)'	System	30 Aug 2020 02:59:35
	System	30 Aug 2020 02:59:35

US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:27:33

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)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-29T19:59:29', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '1c1b81dc-00b0-4574-90b5-955acfc37d5a' User entered 'No (N)'	System	30 Aug 2020 02:59:35
	System	30 Aug 2020 02:59:35



**US3162037**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-29T19:59:32', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '1c1b81dc-00b0-4574-90b5-955acfc37d5a' User entered '29 Aug 2020 19:59'	System	30 Aug 2020 02:59:35
	System	30 Aug 2020 02:59:35

US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:27:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 20:58:14

US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:27:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 20:58:14

US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	28 Aug 2020 20:58:14
User entered 'Day 3'	System	28 Aug 2020 20:58:14

US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:27:33

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-30T17:28:05', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'd7c5fb96-a7a0-4642-832b-32cc8ece6ed8' User entered 'None (0)'	System	31 Aug 2020 00:29:45
	System	31 Aug 2020 00:29:45

US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:27:33

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-30T17:28:13', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'd7c5fb96-a7a0-4642-832b-32cc8ece6ed8' User entered 'None (0)'	System	31 Aug 2020 00:29:45
	System	31 Aug 2020 00:29:45

US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:27:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-30T17:28:16', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'd7c5fb96-a7a0-4642-832b-32cc8ece6ed8' User entered 'None (0)'	System	31 Aug 2020 00:29:45
	System	31 Aug 2020 00:29:45

US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:27:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-30T17:28:19', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'd7c5fb96-a7a0-4642-832b-32cc8ece6ed8' User entered 'None (0)'	System	31 Aug 2020 00:29:45
	System	31 Aug 2020 00:29:45



US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:27:33

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-30T17:28:22', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'd7c5fb96-a7a0-4642-832b-32cc8ece6ed8' User entered 'None (0)'	System	31 Aug 2020 00:29:45
	System	31 Aug 2020 00:29:45

US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:27:33

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-30T17:28:25', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'd7c5fb96-a7a0-4642-832b-32cc8ece6ed8' User entered 'None (0)'	System	31 Aug 2020 00:29:45
	System	31 Aug 2020 00:29:45

US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:27:33

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)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-30T17:28:28', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'd7c5fb96-a7a0-4642-832b-32cc8ece6ed8'	System	31 Aug 2020 00:29:45
User entered 'No (N)'	System	31 Aug 2020 00:29:45

**US3162037**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-30T17:28:30', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'd7c5fb96-a7a0-4642-832b-32cc8ece6ed8' User entered '30 Aug 2020 17:28'	System	31 Aug 2020 00:29:45
	System	31 Aug 2020 00:29:45

US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:27:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 20:58:14

**US3162037**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 20:58:14

US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	28 Aug 2020 20:58:14
User entered 'Day 4'	System	28 Aug 2020 20:58:14

**US3162037**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:27:33**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-31T20:22:12', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '3984b1d7-a4c9-4e03-8974-59398a2de6e6' User entered 'None (0)'	System	01 Sep 2020 03:22:45
	System	01 Sep 2020 03:22:45



US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:27:33

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-31T20:22:16', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '3984b1d7-a4c9-4e03-8974-59398a2de6e6' User entered 'None (0)'	System	01 Sep 2020 03:22:45
	System	01 Sep 2020 03:22:45

US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:27:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-31T20:22:19', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '3984b1d7-a4c9-4e03-8974-59398a2de6e6' User entered 'None (0)'	System	01 Sep 2020 03:22:45
	System	01 Sep 2020 03:22:45

US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:27:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-31T20:22:22', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '3984b1d7-a4c9-4e03-8974-59398a2de6e6' User entered 'None (0)'	System	01 Sep 2020 03:22:45
	System	01 Sep 2020 03:22:45

US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:27:33

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-31T20:22:25', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '3984b1d7-a4c9-4e03-8974-59398a2de6e6' User entered 'None (0)'	System	01 Sep 2020 03:22:45
	System	01 Sep 2020 03:22:45

US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:27:33

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-31T20:22:29', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '3984b1d7-a4c9-4e03-8974-59398a2de6e6' User entered 'None (0)'	System	01 Sep 2020 03:22:45
	System	01 Sep 2020 03:22:45

US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:27:33

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)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-31T20:22:33', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '3984b1d7-a4c9-4e03-8974-59398a2de6e6' User entered 'No (N)'	System	01 Sep 2020 03:22:45
	System	01 Sep 2020 03:22:45

**US3162037**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-08-31T20:22:42', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '3984b1d7-a4c9-4e03-8974-59398a2de6e6' User entered '31 Aug 2020 20:22'	System	01 Sep 2020 03:22:45
	System	01 Sep 2020 03:22:45

US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:27:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 20:58:14



**US3162037**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 20:58:14

US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	28 Aug 2020 20:58:14
User entered 'Day 5'	System	28 Aug 2020 20:58:14

US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:27:33

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-09-01T19:25:26', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'cf3554eb-afb5-43de-8f3f-581182a014f9' User entered 'None (0)'	System	02 Sep 2020 02:25:59
	System	02 Sep 2020 02:25:59

US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:27:33

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-09-01T19:25:29', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'cf3554eb-afb5-43de-8f3f-581182a014f9' User entered 'None (0)'	System	02 Sep 2020 02:25:59
	System	02 Sep 2020 02:25:59

US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:27:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-09-01T19:25:33', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'cf3554eb-afb5-43de-8f3f-581182a014f9' User entered 'None (0)'	System	02 Sep 2020 02:25:59
	System	02 Sep 2020 02:25:59

US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:27:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-09-01T19:25:41', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'cf3554eb-afb5-43de-8f3f-581182a014f9' User entered 'None (0)'	System	02 Sep 2020 02:25:59
	System	02 Sep 2020 02:25:59

**US3162037**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:27:33**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-09-01T19:25:46', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'cf3554eb-afb5-43de-8f3f-581182a014f9' User entered 'None (0)'	System	02 Sep 2020 02:25:59
	System	02 Sep 2020 02:25:59

**US3162037**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:27:33**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-09-01T19:25:49', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'cf3554eb-afb5-43de-8f3f-581182a014f9' User entered 'None (0)'	System	02 Sep 2020 02:25:59
	System	02 Sep 2020 02:25:59



US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:27:33

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)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-09-01T19:25:51', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'cf3554eb-afb5-43de-8f3f-581182a014f9' User entered 'No (N)'	System	02 Sep 2020 02:25:59
	System	02 Sep 2020 02:25:59

**US3162037**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-09-01T19:25:57', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'cf3554eb-afb5-43de-8f3f-581182a014f9' User entered '01 Sep 2020 19:25'	System	02 Sep 2020 02:25:59
	System	02 Sep 2020 02:25:59

US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:27:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 20:58:14

**US3162037**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 20:58:14

US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	28 Aug 2020 20:58:14
User entered 'Day 6'	System	28 Aug 2020 20:58:14

US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:27:33

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-09-02T22:21:52', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '1410faee-c657-4956-9ac8-a3d9e9791d38' User entered 'None (0)'	System	03 Sep 2020 05:22:10
	System	03 Sep 2020 05:22:10

US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:27:33

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-09-02T22:21:54', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '1410faee-c657-4956-9ac8-a3d9e9791d38' User entered 'None (0)'	System	03 Sep 2020 05:22:10
	System	03 Sep 2020 05:22:10

US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:27:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-09-02T22:21:57', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '1410faee-c657-4956-9ac8-a3d9e9791d38' User entered 'None (0)'	System	03 Sep 2020 05:22:10
	System	03 Sep 2020 05:22:10



US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:27:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-09-02T22:21:59', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '1410faee-c657-4956-9ac8-a3d9e9791d38' User entered 'None (0)'	System	03 Sep 2020 05:22:10
	System	03 Sep 2020 05:22:10

US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:27:33

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-09-02T22:22:01', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '1410faee-c657-4956-9ac8-a3d9e9791d38' User entered 'None (0)'	System	03 Sep 2020 05:22:10
	System	03 Sep 2020 05:22:10

US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:27:33

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-09-02T22:22:03', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '1410faee-c657-4956-9ac8-a3d9e9791d38' User entered 'None (0)'	System	03 Sep 2020 05:22:10
	System	03 Sep 2020 05:22:10

US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:27:33

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)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-09-02T22:22:06', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '1410faee-c657-4956-9ac8-a3d9e9791d38' User entered 'No (N)'	System	03 Sep 2020 05:22:10
	System	03 Sep 2020 05:22:10

**US3162037**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-09-02T22:22:08', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '1410faee-c657-4956-9ac8-a3d9e9791d38' User entered '02 Sep 2020 22:22'	System	03 Sep 2020 05:22:10
	System	03 Sep 2020 05:22:10

US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:27:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 20:58:14

**US3162037**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 20:58:14

US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:27:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	28 Aug 2020 20:58:14
User entered 'Day 7'	System	28 Aug 2020 20:58:14



**US3162037**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:27:33**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-09-03T17:09:10', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '2b25c50f-230c-4b77-936a-96bbfda52a96' User entered 'None (0)'	System	04 Sep 2020 00:09:31
	System	04 Sep 2020 00:09:31

**US3162037**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:27:33**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-09-03T17:09:13', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '2b25c50f-230c-4b77-936a-96bbfda52a96' User entered 'None (0)'	System	04 Sep 2020 00:09:31
	System	04 Sep 2020 00:09:31

US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:27:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-09-03T17:09:16', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '2b25c50f-230c-4b77-936a-96bbfda52a96' User entered 'None (0)'	System	04 Sep 2020 00:09:31
	System	04 Sep 2020 00:09:31

US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:27:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-09-03T17:09:18', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '2b25c50f-230c-4b77-936a-96bbfda52a96' User entered 'None (0)'	System	04 Sep 2020 00:09:31
	System	04 Sep 2020 00:09:31

**US3162037**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:27:33**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-09-03T17:09:20', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '2b25c50f-230c-4b77-936a-96bbfda52a96' User entered 'None (0)'	System	04 Sep 2020 00:09:31
	System	04 Sep 2020 00:09:31

US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:27:33

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-09-03T17:09:23', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '2b25c50f-230c-4b77-936a-96bbfda52a96' User entered 'None (0)'	System	04 Sep 2020 00:09:31
	System	04 Sep 2020 00:09:31

US3162037

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:27:33

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)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-09-03T17:09:26', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '2b25c50f-230c-4b77-936a-96bbfda52a96' User entered 'No (N)'	System	04 Sep 2020 00:09:31
	System	04 Sep 2020 00:09:31

**US3162037**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-09-03T17:09:29', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '2b25c50f-230c-4b77-936a-96bbfda52a96' User entered '03 Sep 2020 17:09'	System	04 Sep 2020 00:09:31
	System	04 Sep 2020 00:09:31



**US3162037**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 20:58:14

**US3162037**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:27:33**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 20:58:14

US3162037

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:27:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	07 Sep 2020 17:47:38

US3162037

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4)	13 Feb 2021 01:34:22
	(b) (4)	
User entered '04 Sep 2020'	Cynthia Kunakom (b) (4)	07 Sep 2020 17:47:38
	(b) (4)	

US3162037

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:27:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'Contact Made (CONTACT MADE)'	Cynthia Kunakom (b) (4) (b) (4)	07 Sep 2020 17:47:38

US3162037

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:27:33

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	07 Sep 2020 17:47:38

US3162037

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:27:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	07 Sep 2020 17:47:43

**US3162037**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:27:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User entered 'I'	System	07 Sep 2020 17:47:43



US3162037

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:27:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	21 Sep 2020 14:24:13

US3162037

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:27:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4)	13 Feb 2021 01:34:22
	(b) (4)	
User entered '11 Sep 2020'	Cynthia Kunakom (b) (4)	21 Sep 2020 14:24:13
	(b) (4)	

US3162037

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:27:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'Contact Made (CONTACT MADE)'	Cynthia Kunakom (b) (4) (b) (4)	21 Sep 2020 14:24:13

US3162037

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:27:33

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	21 Sep 2020 14:24:13

US3162037

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:27:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	21 Sep 2020 14:24:19

US3162037

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:27:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User entered 'I'	System	21 Sep 2020 14:24:19

US3162037

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:27:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	21 Sep 2020 14:24:50

**US3162037**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4)	13 Feb 2021 01:35:19
	(b) (4)	
User entered '18 Sep 2020'	Cynthia Kunakom (b) (4)	21 Sep 2020 14:24:50
	(b) (4)	



**US3162037**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:27:33**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'Contact Made (CONTACT MADE)'	Cynthia Kunakom (b) (4) (b) (4)	21 Sep 2020 14:24:50

US3162037

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:27:33

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	21 Sep 2020 14:24:50

US3162037

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:27:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	21 Sep 2020 14:25:10

**US3162037**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:27:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User entered 'I'	System	21 Sep 2020 14:25:10

**US3162037**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:27:33**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:25:37

**US3162037**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:27:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '25 Sep 2020'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:25:37

US3162037

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:27:33

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 04:04:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'Clinic (Clinic)'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:25:37

**US3162037**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:27:33**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User entered 'VISIT3'	System	28 Sep 2020 16:25:37



US3162037

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:26:02

US3162037

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '25 Sep 2020'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:26:02

**US3162037**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:27:33**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '12:04'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:26:02

**US3162037**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:27:33**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User entered '25 Sep 2020 12:04'	System	28 Sep 2020 16:26:02

US3162037

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '36.4' C	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:26:02

US3162037

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'Oral (Oral)'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:26:02

US3162037

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:26:02

US3162037

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '56'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:26:02



**US3162037**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:27:33**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User entered 'bpm'	System	28 Sep 2020 16:26:02

US3162037

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '11'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:26:02

US3162037

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User entered 'breaths/min'	System	28 Sep 2020 16:26:02

US3162037

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '113'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:26:02

US3162037

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User entered 'mmHg'	System	28 Sep 2020 16:26:02

US3162037

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '63'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:26:02

US3162037

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:33

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User entered 'mmHg'	System	28 Sep 2020 16:26:02

US3162037

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:33

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52



**US3162037**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:27:33**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52

US3162037

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:27:33

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'No (N)' reason for change: Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	15 Oct 2020 14:17:38
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:26:38

US3162037

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:27:33

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User signature succeeded.	Judith Kirstein (b) (4)	13 Feb 2021 01:35:19
	(b) (4)	
User entered empty; reason for change Data Entry Error	Cynthia Kunakom (b) (4)	15 Oct 2020 14:17:38
	(b) (4)	
User entered '25 Sep 2020'	Cynthia Kunakom (b) (4)	28 Sep 2020 16:26:38
	(b) (4)	

US3162037

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:27:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:26:57

US3162037

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:27:33

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '25 Sep 2020'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:26:57

US3162037

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:27:33

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '12:46'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:26:57

**US3162037**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:27:33**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User entered '25 Sep 2020 12:46'	System	28 Sep 2020 16:26:57

US3162037

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:27:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:27:01



**US3162037**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:27:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:52
User entered 'I'	System	28 Sep 2020 16:27:01

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	31 Jul 2020 22:07:27
User entered 'Day 64'	System	31 Jul 2020 22:07:27

US3162037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

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)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-09-30T19:15:56', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '78562579-fe8f-4b74-a185-84f81bcd6e1f' User entered 'No (N)'	System	01 Oct 2020 02:16:15
	System	01 Oct 2020 02:16:15

US3162037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Have you been exposed to someone with 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)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-09-30T19:15:53', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '78562579-fe8f-4b74-a185-84f81bcd6e1f'	System	01 Oct 2020 02:16:15
User entered 'No (N)'	System	01 Oct 2020 02:16:15

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-09-30T19:16:11', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '78562579-fe8f-4b74-a185-84f81bcd6e1f' User entered '30 Sep 2020 19:16:11'	System	01 Oct 2020 02:16:15
	System	01 Oct 2020 02:16:15

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	31 Jul 2020 22:07:27
User entered '30 Sep 2020 00:01'	System	31 Jul 2020 22:07:27

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	31 Jul 2020 22:07:27
User entered '04 Oct 2020 23:59'	System	31 Jul 2020 22:07:27

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	31 Jul 2020 22:07:27
User entered 'Day 71'	System	31 Jul 2020 22:07:27



US3162037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

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)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-10-07T08:40:28', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'e31a749b-8ba7-41b3-9dbc-eba18ae4d8a2'	System	07 Oct 2020 15:40:50
User entered 'No (N)'	System	07 Oct 2020 15:40:50

US3162037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Have you been exposed to someone with 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)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-10-07T08:40:34', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'e31a749b-8ba7-41b3-9dbc-eba18ae4d8a2'	System	07 Oct 2020 15:40:50
User entered 'No (N)'	System	07 Oct 2020 15:40:50

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-10-07T08:40:46', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'e31a749b-8ba7-41b3-9dbc-eba18ae4d8a2' User entered '07 Oct 2020 08:40:46'	System	07 Oct 2020 15:40:50
	System	07 Oct 2020 15:40:50

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	31 Jul 2020 22:07:27
User entered '07 Oct 2020 00:01'	System	31 Jul 2020 22:07:27

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	31 Jul 2020 22:07:27
User entered '11 Oct 2020 23:59'	System	31 Jul 2020 22:07:27

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	31 Jul 2020 22:07:27
User entered 'Day 78'	System	31 Jul 2020 22:07:27

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[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)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-10-14T07:47:50', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '441f9c41-bfc2-4ee1-9b7b-2089bd7349d5'	System	14 Oct 2020 14:48:06
User entered 'No (N)'	System	14 Oct 2020 14:48:06

US3162037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Have you been exposed to someone with 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)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-10-14T07:47:56', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '441f9c41-bfc2-4ee1-9b7b-2089bd7349d5'	System	14 Oct 2020 14:48:06
User entered 'No (N)'	System	14 Oct 2020 14:48:06



**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-10-14T07:48:02', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '441f9c41-bfc2-4ee1-9b7b-2089bd7349d5' User entered '14 Oct 2020 07:48:02'	System	14 Oct 2020 14:48:06
	System	14 Oct 2020 14:48:06

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	31 Jul 2020 22:07:27
User entered '14 Oct 2020 00:01'	System	31 Jul 2020 22:07:27

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	31 Jul 2020 22:07:27
User entered '18 Oct 2020 23:59'	System	31 Jul 2020 22:07:27

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	31 Jul 2020 22:07:27
User entered 'Day 92'	System	31 Jul 2020 22:07:27

US3162037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

[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)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-10-28T10:30:16', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '00ac8516-454f-4fb8-89a7-5e6e9f0bc437'	System	28 Oct 2020 17:30:41
User entered 'No (N)'	System	28 Oct 2020 17:30:41

US3162037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Have you been exposed to someone with 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)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-10-28T10:30:22', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '00ac8516-454f-4fb8-89a7-5e6e9f0bc437'	System	28 Oct 2020 17:30:41
User entered 'No (N)'	System	28 Oct 2020 17:30:41

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-10-28T10:30:29', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '00ac8516-454f-4fb8-89a7-5e6e9f0bc437' User entered '28 Oct 2020 10:30:29'	System	28 Oct 2020 17:30:41
	System	28 Oct 2020 17:30:41

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	31 Jul 2020 22:07:27
User entered '28 Oct 2020 00:01'	System	31 Jul 2020 22:07:27



**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	31 Jul 2020 22:07:27
User entered '01 Nov 2020 23:59'	System	31 Jul 2020 22:07:27

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	31 Jul 2020 22:07:27
User entered 'Day 99'	System	31 Jul 2020 22:07:27

US3162037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

[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)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-11-04T09:27:28', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'd7f76b23-408d-4747-9e55-1dda13409a43'	System	04 Nov 2020 17:27:49
User entered 'No (N)'	System	04 Nov 2020 17:27:49

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

Have you been exposed to someone with 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)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-11-04T09:27:40', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'd7f76b23-408d-4747-9e55-1dda13409a43'	System	04 Nov 2020 17:27:49
User entered 'No (N)'	System	04 Nov 2020 17:27:49

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-11-04T09:27:45', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'd7f76b23-408d-4747-9e55-1dda13409a43'	System	04 Nov 2020 17:27:49
User entered '04 Nov 2020 09:27:45'	System	04 Nov 2020 17:27:49

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	31 Jul 2020 22:07:27
User entered '04 Nov 2020 00:01'	System	31 Jul 2020 22:07:27

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	31 Jul 2020 22:07:27
User entered '08 Nov 2020 23:59'	System	31 Jul 2020 22:07:27

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	31 Jul 2020 22:07:27
User entered 'Day 106'	System	31 Jul 2020 22:07:27



US3162037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

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)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-11-11T10:19:55', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'bba77eca-16bd-4104-8f70-6eb5e353535c' User entered 'No (N)'	System	11 Nov 2020 18:20:11
	System	11 Nov 2020 18:20:11

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

Have you been exposed to someone with 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)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-11-11T10:20:01', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'bba77eca-16bd-4104-8f70-6eb5e353535c'	System	11 Nov 2020 18:20:11
User entered 'No (N)'	System	11 Nov 2020 18:20:11

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-11-11T10:20:07', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'bba77eca-16bd-4104-8f70-6eb5e353535c' User entered '11 Nov 2020 10:20:07'	System	11 Nov 2020 18:20:11
	System	11 Nov 2020 18:20:11

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	31 Jul 2020 22:07:27
User entered '11 Nov 2020 00:01'	System	31 Jul 2020 22:07:27

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	31 Jul 2020 22:07:27
User entered '15 Nov 2020 23:59'	System	31 Jul 2020 22:07:27

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	31 Jul 2020 22:07:27
User entered 'Day 113'	System	31 Jul 2020 22:07:27

US3162037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

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)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-11-18T19:17:56', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'e894e3ce-f591-40e7-a38a-f59a3b3a5980'	System	19 Nov 2020 03:18:09
User entered 'No (N)'	System	19 Nov 2020 03:18:09

US3162037

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:27:33

Have you been exposed to someone with 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)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-11-18T19:18:01', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'e894e3ce-f591-40e7-a38a-f59a3b3a5980'	System	19 Nov 2020 03:18:09
User entered 'No (N)'	System	19 Nov 2020 03:18:09



**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-11-18T19:18:05', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'e894e3ce-f591-40e7-a38a-f59a3b3a5980' User entered '18 Nov 2020 19:18:05'	System	19 Nov 2020 03:18:09
	System	19 Nov 2020 03:18:09

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	31 Jul 2020 22:07:27
User entered '18 Nov 2020 00:01'	System	31 Jul 2020 22:07:27

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:48:36
Data entry locked.	System	31 Jul 2020 22:07:27
User entered '22 Nov 2020 23:59'	System	31 Jul 2020 22:07:27

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 11:09:32

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[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 (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-11-19T09:03:09', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '169598e7-6626-4bf9-906c-19e86828eb0d'	System	19 Nov 2020 17:03:48
User entered 'No (N)'	System	19 Nov 2020 17:03:48

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Have you been exposed to someone with 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 (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-11-19T09:03:23', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '169598e7-6626-4bf9-906c-19e86828eb0d' User entered 'No (N)'	System	19 Nov 2020 17:03:48
	System	19 Nov 2020 17:03:48

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-11-19T09:03:27', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '169598e7-6626-4bf9-906c-19e86828eb0d' User entered '19 Nov 2020 09:03:27'	System	19 Nov 2020 17:03:48
	System	19 Nov 2020 17:03:48

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '15 Nov 2020 00:01'	System	19 Nov 2020 11:09:32



**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '19 Nov 2020 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 11:09:32

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[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 (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-11-22T08:22:21', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'a6bb9383-6208-4bb7-a5d6-6872bd30006c'	System	22 Nov 2020 16:22:43
User entered 'No (N)'	System	22 Nov 2020 16:22:43

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

Have you been exposed to someone with 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 (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-11-22T08:22:34', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'a6bb9383-6208-4bb7-a5d6-6872bd30006c'	System	22 Nov 2020 16:22:43
User entered 'No (N)'	System	22 Nov 2020 16:22:43

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-11-22T08:22:40', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'a6bb9383-6208-4bb7-a5d6-6872bd30006c' User entered '22 Nov 2020 08:22:40'	System	22 Nov 2020 16:22:43
	System	22 Nov 2020 16:22:43

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 11:09:32



**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[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 (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-11-29T09:43:16', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'b05ba445-ae19-4d3e-bdbc-48fec5a9d465'	System	29 Nov 2020 17:43:28
User entered 'No (N)'	System	29 Nov 2020 17:43:28

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Have you been exposed to someone with 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 (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-11-29T09:43:21', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'b05ba445-ae19-4d3e-bdbc-48fec5a9d465'	System	29 Nov 2020 17:43:28
User entered 'No (N)'	System	29 Nov 2020 17:43:28

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-11-29T09:43:26', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'b05ba445-ae19-4d3e-bdbc-48fec5a9d465'	System	29 Nov 2020 17:43:28
User entered '29 Nov 2020 09:43:26'	System	29 Nov 2020 17:43:28

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 11:09:32

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[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 (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-12-06T19:36:54', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '02d3d408-6ffe-4a4b-baa5-5c4c7f3b8a2b'	System	07 Dec 2020 03:37:54
User entered 'No (N)'	System	07 Dec 2020 03:37:54

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

Have you been exposed to someone with 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 (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-12-06T19:37:00', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '02d3d408-6ffe-4a4b-baa5-5c4c7f3b8a2b'	System	07 Dec 2020 03:37:54
User entered 'No (N)'	System	07 Dec 2020 03:37:54



**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-12-06T19:37:04', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '02d3d408-6ffe-4a4b-baa5-5c4c7f3b8a2b' User entered '06 Dec 2020 19:37:04'	System	07 Dec 2020 03:37:54
	System	07 Dec 2020 03:37:54

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 11:09:32

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[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 (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-12-13T19:11:52', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '3fe512c3-6125-44b4-b61d-e439c3f095b5'	System	14 Dec 2020 03:12:28
User entered 'No (N)'	System	14 Dec 2020 03:12:28

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

Have you been exposed to someone with 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 (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-12-13T19:12:22', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '3fe512c3-6125-44b4-b61d-e439c3f095b5'	System	14 Dec 2020 03:12:28
User entered 'No (N)'	System	14 Dec 2020 03:12:28

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-12-13T19:12:26', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '3fe512c3-6125-44b4-b61d-e439c3f095b5'	System	14 Dec 2020 03:12:28
User entered '13 Dec 2020 19:12:26'	System	14 Dec 2020 03:12:28

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 11:09:32



**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 11:09:32

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[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 (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-12-20T10:25:53', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'bc17843f-e471-4d61-a334-ddae39fb2741' User entered 'No (N)'	System	20 Dec 2020 18:26:55
	System	20 Dec 2020 18:26:55

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

Have you been exposed to someone with 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 (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-12-20T10:26:18', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'bc17843f-e471-4d61-a334-ddae39fb2741' User entered 'Yes (Y)'	System	20 Dec 2020 18:26:55
	System	20 Dec 2020 18:26:55

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Please 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 (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-12-20T10:26:31', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'bc17843f-e471-4d61-a334-ddae39fb2741'	System	20 Dec 2020 18:26:55
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	20 Dec 2020 18:26:55

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-12-20T10:26:43', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'bc17843f-e471-4d61-a334-ddae39fb2741' User entered '20 Dec 2020 10:26:43'	System	20 Dec 2020 18:26:55
	System	20 Dec 2020 18:26:55

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 11:09:32



**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 11:09:32

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[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 (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-12-27T00:01:33', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'f9ca38b9-6706-404e-949f-a82b6ba57ca7' User entered 'No (N)'	System	27 Dec 2020 08:01:48
	System	27 Dec 2020 08:01:48

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

Have you been exposed to someone with 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 (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-12-27T00:01:41', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'f9ca38b9-6706-404e-949f-a82b6ba57ca7'	System	27 Dec 2020 08:01:48
User entered 'No (N)'	System	27 Dec 2020 08:01:48

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2020-12-27T00:01:45', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'f9ca38b9-6706-404e-949f-a82b6ba57ca7' User entered '27 Dec 2020 00:01:45'	System	27 Dec 2020 08:01:48
	System	27 Dec 2020 08:01:48

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 11:09:32

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[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 (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-01-03T10:17:55', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '0e4e8e48-6dcf-4594-9013-9e134a355006' User entered 'No (N)'	System	03 Jan 2021 18:18:15
	System	03 Jan 2021 18:18:15



**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Have you been exposed to someone with 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 (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-01-03T10:18:05', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '0e4e8e48-6dcf-4594-9013-9e134a355006' User entered 'No (N)'	System	03 Jan 2021 18:18:15
	System	03 Jan 2021 18:18:15

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-01-03T10:18:13', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '0e4e8e48-6dcf-4594-9013-9e134a355006' User entered '03 Jan 2021 10:18:13'	System	03 Jan 2021 18:18:15
	System	03 Jan 2021 18:18:15

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 11:09:32

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[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 (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-01-10T09:47:47', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'a230c4a1-382e-40bc-ac17-e06b5d683b1e' User entered 'No (N)'	System	10 Jan 2021 17:48:04
	System	10 Jan 2021 17:48:04

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Have you been exposed to someone with 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 (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-01-10T09:47:55', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'a230c4a1-382e-40bc-ac17-e06b5d683b1e' User entered 'No (N)'	System	10 Jan 2021 17:48:04
	System	10 Jan 2021 17:48:04

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-01-10T09:48:01', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'a230c4a1-382e-40bc-ac17-e06b5d683b1e' User entered '10 Jan 2021 09:48:01'	System	10 Jan 2021 17:48:04
	System	10 Jan 2021 17:48:04



**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 11:09:32

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[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 (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-01-17T09:53:06', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'de59dcea-980f-455d-8653-735eef6f1c67'	System	17 Jan 2021 17:53:16
User entered 'No (N)'	System	17 Jan 2021 17:53:16

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

Have you been exposed to someone with 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 (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-01-17T09:53:10', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'de59dcea-980f-455d-8653-735eef6f1c67'	System	17 Jan 2021 17:53:16
User entered 'No (N)'	System	17 Jan 2021 17:53:16

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-01-17T09:53:13', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'de59dcea-980f-455d-8653-735eef6f1c67' User entered '17 Jan 2021 09:53:13'	System	17 Jan 2021 17:53:16
	System	17 Jan 2021 17:53:16

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 11:09:32



**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 11:09:32

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[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 (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-01-24T19:31:55', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'c8b1c890-3ce1-4170-8b02-499362987b59'	System	25 Jan 2021 03:32:04
User entered 'No (N)'	System	25 Jan 2021 03:32:04

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

Have you been exposed to someone with 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 (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-01-24T19:31:59', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'c8b1c890-3ce1-4170-8b02-499362987b59'	System	25 Jan 2021 03:32:04
User entered 'No (N)'	System	25 Jan 2021 03:32:04

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-01-24T19:32:02', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'c8b1c890-3ce1-4170-8b02-499362987b59'	System	25 Jan 2021 03:32:04
User entered '24 Jan 2021 19:32:02'	System	25 Jan 2021 03:32:04

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 11:09:32

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[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 (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-01-31T09:46:10', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '00fdb2e4-6aaf-422f-a5f6-6f6c16b8e7bd' User entered 'No (N)'	System	31 Jan 2021 17:46:24
	System	31 Jan 2021 17:46:24



**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

Have you been exposed to someone with 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 (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-01-31T09:46:16', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '00fdb2e4-6aaf-422f-a5f6-6f6c16b8e7bd'	System	31 Jan 2021 17:46:24
User entered 'No (N)'	System	31 Jan 2021 17:46:24

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-01-31T09:46:20', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '00fdb2e4-6aaf-422f-a5f6-6f6c16b8e7bd' User entered '31 Jan 2021 09:46:20'	System	31 Jan 2021 17:46:24
	System	31 Jan 2021 17:46:24

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 11:09:32

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[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 (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-02-07T20:03:30', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '76d862bb-7166-430e-9290-5c0fe1c4b508'	System	08 Feb 2021 04:03:40
User entered 'No (N)'	System	08 Feb 2021 04:03:40

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

Have you been exposed to someone with 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 (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-02-07T20:03:33', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '76d862bb-7166-430e-9290-5c0fe1c4b508'	System	08 Feb 2021 04:03:40
User entered 'No (N)'	System	08 Feb 2021 04:03:40

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-02-07T20:03:37', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '76d862bb-7166-430e-9290-5c0fe1c4b508'	System	08 Feb 2021 04:03:40
User entered '07 Feb 2021 20:03:37'	System	08 Feb 2021 04:03:40



**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 11:09:32

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[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 (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-02-17T12:37:25', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '69daaa81-2bf7-4ee6-b18a-72bd1acb4e34'	System	17 Feb 2021 20:37:37
User entered 'No (N)'	System	17 Feb 2021 20:37:37

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

Have you been exposed to someone with 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 (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-02-17T12:37:27', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '69daaa81-2bf7-4ee6-b18a-72bd1acb4e34'	System	17 Feb 2021 20:37:37
User entered 'No (N)'	System	17 Feb 2021 20:37:37

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-02-17T12:37:32', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '69daaa81-2bf7-4ee6-b18a-72bd1acb4e34' User entered '17 Feb 2021 12:37:32'	System	17 Feb 2021 20:37:37
	System	17 Feb 2021 20:37:37

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 11:09:32



**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 11:09:32

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[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 (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-02-21T08:28:37', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'acd6da11-5dad-41bb-b3f3-23c6a04bd0e9' User entered 'No (N)'	System	21 Feb 2021 16:28:48
	System	21 Feb 2021 16:28:48

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

Have you been exposed to someone with 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 (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-02-21T08:28:41', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'acd6da11-5dad-41bb-b3f3-23c6a04bd0e9' User entered 'No (N)'	System	21 Feb 2021 16:28:48
	System	21 Feb 2021 16:28:48

**US3162037**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-02-21T08:28:44', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'acd6da11-5dad-41bb-b3f3-23c6a04bd0e9' User entered '21 Feb 2021 08:28:44'	System	21 Feb 2021 16:28:48
	System	21 Feb 2021 16:28:48

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[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 (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-02-28T19:57:51-08:00', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '180bfddc-ab98-4baa-9533-15b6288aaca'	System	01 Mar 2021 03:58:06
User entered 'No (N)'	System	01 Mar 2021 03:58:06



**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Have you been exposed to someone with 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 (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-02-28T19:57:57-08:00', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '180bfddc-ab98-4baa-9533-15b6288aaca'	System	01 Mar 2021 03:58:06
User entered 'No (N)'	System	01 Mar 2021 03:58:06

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-02-28T19:58:00-08:00', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '180bfddc-ab98-4baa-9533-15b6288aacao' User entered '28 Feb 2021 19:58:00'	System	01 Mar 2021 03:58:06
	System	01 Mar 2021 03:58:06

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[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 (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-03-07T08:49:46-08:00', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '7023fe6b-c92f-44cb-af97-c26c5b74db16'	System	07 Mar 2021 16:49:57
User entered 'No (N)'	System	07 Mar 2021 16:49:57

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

Have you been exposed to someone with 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 (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-03-07T08:49:51-08:00', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '7023fe6b-c92f-44cb-af97-c26c5b74db16'	System	07 Mar 2021 16:49:57
User entered 'No (N)'	System	07 Mar 2021 16:49:57

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-03-07T08:49:55-08:00', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '7023fe6b-c92f-44cb-af97-c26c5b74db16' User entered '07 Mar 2021 08:49:55'	System	07 Mar 2021 16:49:57
	System	07 Mar 2021 16:49:57



**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[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 (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-03-14T08:49:42-07:00', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '91c3c92e-251f-414a-8e57-615ef6e40455'	System	14 Mar 2021 15:49:53
User entered 'No (N)'	System	14 Mar 2021 15:49:53

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

Have you been exposed to someone with 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 (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-03-14T08:49:46-07:00', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '91c3c92e-251f-414a-8e57-615ef6e40455'	System	14 Mar 2021 15:49:53
User entered 'No (N)'	System	14 Mar 2021 15:49:53

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-03-14T08:49:49-07:00', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '91c3c92e-251f-414a-8e57-615ef6e40455'	System	14 Mar 2021 15:49:53
User entered '14 Mar 2021 08:49:49'	System	14 Mar 2021 15:49:53

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 11:09:32



**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[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 (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-03-21T11:12:03-07:00', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '145801cc-c48c-495b-810f-6b9e4afb470d'	System	21 Mar 2021 18:12:14
User entered 'No (N)'	System	21 Mar 2021 18:12:14

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Have you been exposed to someone with 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 (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-03-21T11:12:06-07:00', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '145801cc-c48c-495b-810f-6b9e4afb470d'	System	21 Mar 2021 18:12:14
User entered 'No (N)'	System	21 Mar 2021 18:12:14

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-03-21T11:12:10-07:00', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '145801cc-c48c-495b-810f-6b9e4afb470d' User entered '21 Mar 2021 11:12:10'	System	21 Mar 2021 18:12:14
	System	21 Mar 2021 18:12:14

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[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 (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-03-28T10:56:31-07:00', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'f48d8289-66dc-4e34-af9b-85af9be2cc8e'	System	28 Mar 2021 17:57:59
User entered 'Yes (Y)'	System	28 Mar 2021 17:57:59



**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

Have you been exposed to someone with 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 (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-03-28T10:56:41-07:00', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'f48d8289-66dc-4e34-af9b-85af9be2cc8e'	System	28 Mar 2021 17:57:59
User entered 'No (N)'	System	28 Mar 2021 17:57:59

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[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 (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-03-28T10:56:55-07:00', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'f48d8289-66dc-4e34-af9b-85af9be2cc8e'	System	28 Mar 2021 17:57:59
User entered 'Yes (Y)'	System	28 Mar 2021 17:57:59

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Fever \(Temperature  \$\geq\$  100.4°F/38°C\)](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-03-28T10:57:19-07:00', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'f48d8289-66dc-4e34-af9b-85af9be2cc8e'	System	28 Mar 2021 17:57:59
User entered '1'	System	28 Mar 2021 17:57:59

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-03-28T10:57:19-07:00', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'f48d8289-66dc-4e34-af9b-85af9be2cc8e'	System	28 Mar 2021 17:57:59
User entered '0'	System	28 Mar 2021 17:57:59

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-03-28T10:57:19-07:00', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'f48d8289-66dc-4e34-af9b-85af9be2cc8e' User entered '0'	System	28 Mar 2021 17:57:59
	System	28 Mar 2021 17:57:59

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-03-28T10:57:19-07:00', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'f48d8289-66dc-4e34-af9b-85af9be2cc8e'	System	28 Mar 2021 17:57:59
User entered '0'	System	28 Mar 2021 17:57:59

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-03-28T10:57:19-07:00', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'f48d8289-66dc-4e34-af9b-85af9be2cc8e'	System	28 Mar 2021 17:57:59
User entered '0'	System	28 Mar 2021 17:57:59

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-03-28T10:57:19-07:00', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'f48d8289-66dc-4e34-af9b-85af9be2cc8e'	System	28 Mar 2021 17:57:59
User entered '0'	System	28 Mar 2021 17:57:59



**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-03-28T10:57:19-07:00', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'f48d8289-66dc-4e34-af9b-85af9be2cc8e'	System	28 Mar 2021 17:57:59
User entered '1'	System	28 Mar 2021 17:57:59

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-03-28T10:57:19-07:00', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'f48d8289-66dc-4e34-af9b-85af9be2cc8e'	System	28 Mar 2021 17:57:59
User entered '1'	System	28 Mar 2021 17:57:59

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-03-28T10:57:19-07:00', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'f48d8289-66dc-4e34-af9b-85af9be2cc8e'	System	28 Mar 2021 17:57:59
User entered '0'	System	28 Mar 2021 17:57:59

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-03-28T10:57:19-07:00', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'f48d8289-66dc-4e34-af9b-85af9be2cc8e'	System	28 Mar 2021 17:57:59
User entered '0'	System	28 Mar 2021 17:57:59

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-03-28T10:57:19-07:00', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'f48d8289-66dc-4e34-af9b-85af9be2cc8e'	System	28 Mar 2021 17:57:59
User entered '0'	System	28 Mar 2021 17:57:59

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-03-28T10:57:19-07:00', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'f48d8289-66dc-4e34-af9b-85af9be2cc8e'	System	28 Mar 2021 17:57:59
User entered '0'	System	28 Mar 2021 17:57:59

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-03-28T10:57:19-07:00', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'f48d8289-66dc-4e34-af9b-85af9be2cc8e' User entered '1'	System	28 Mar 2021 17:57:59

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-03-28T10:57:19-07:00', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'f48d8289-66dc-4e34-af9b-85af9be2cc8e' User entered '0'	System	28 Mar 2021 17:57:59
	System	28 Mar 2021 17:57:59



**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-03-28T10:57:19-07:00', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'f48d8289-66dc-4e34-af9b-85af9be2cc8e'	System	28 Mar 2021 17:57:59
User entered '0'	System	28 Mar 2021 17:57:59

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-03-28T10:57:19-07:00', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'f48d8289-66dc-4e34-af9b-85af9be2cc8e'	System	28 Mar 2021 17:57:59
User entered '0'	System	28 Mar 2021 17:57:59

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-03-28T10:57:19-07:00', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'f48d8289-66dc-4e34-af9b-85af9be2cc8e'	System	28 Mar 2021 17:57:59
User entered '0'	System	28 Mar 2021 17:57:59

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Please 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 (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-03-28T10:57:31-07:00', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'f48d8289-66dc-4e34-af9b-85af9be2cc8e'	System	28 Mar 2021 17:57:59
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	28 Mar 2021 17:57:59

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[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 (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-03-28T10:57:40-07:00', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'f48d8289-66dc-4e34-af9b-85af9be2cc8e'	System	28 Mar 2021 17:57:59
User entered 'No (N)'	System	28 Mar 2021 17:57:59

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-03-28T10:57:48-07:00', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'f48d8289-66dc-4e34-af9b-85af9be2cc8e' User entered '28 Mar 2021 10:57:48'	System	28 Mar 2021 17:57:59
	System	28 Mar 2021 17:57:59

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 11:09:32



**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[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 (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-04-04T08:16:38-07:00', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '6abae3c4-f24b-438f-85a4-748203c19fb9'	System	04 Apr 2021 15:16:49
User entered 'No (N)'	System	04 Apr 2021 15:16:49

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

Have you been exposed to someone with 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 (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-04-04T08:16:43-07:00', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '6abae3c4-f24b-438f-85a4-748203c19fb9'	System	04 Apr 2021 15:16:49
User entered 'No (N)'	System	04 Apr 2021 15:16:49

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-04-04T08:16:47-07:00', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '6abae3c4-f24b-438f-85a4-748203c19fb9'	System	04 Apr 2021 15:16:49
User entered '04 Apr 2021 08:16:47'	System	04 Apr 2021 15:16:49

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[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 (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-04-12T10:24:46-07:00', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '3cc8f9e9-f5a2-495e-a401-7b6b6e5e4a4f' User entered 'No (N)'	System	12 Apr 2021 17:28:31
	System	12 Apr 2021 17:28:31



**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

Have you been exposed to someone with 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 (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-04-12T10:24:50-07:00', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '3cc8f9e9-f5a2-495e-a401-7b6b6e5e4a4f' User entered 'No (N)'	System	12 Apr 2021 17:28:31

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-04-12T10:24:54-07:00', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '3cc8f9e9-f5a2-495e-a401-7b6b6e5e4a4f' User entered '12 Apr 2021 10:24:54'	System	12 Apr 2021 17:28:31
	System	12 Apr 2021 17:28:31

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[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 (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-04-18T19:37:18-07:00', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '7a769440-6133-4864-aca7-041b97fa6907'	System	19 Apr 2021 02:37:31
User entered 'No (N)'	System	19 Apr 2021 02:37:31

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Have you been exposed to someone with 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 (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-04-18T19:37:23-07:00', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '7a769440-6133-4864-aca7-041b97fa6907'	System	19 Apr 2021 02:37:31
User entered 'No (N)'	System	19 Apr 2021 02:37:31

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-04-18T19:37:27-07:00', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '7a769440-6133-4864-aca7-041b97fa6907'	System	19 Apr 2021 02:37:31
User entered '18 Apr 2021 19:37:27'	System	19 Apr 2021 02:37:31



**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[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 (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-04-26T11:30:48-07:00', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'fabf6e90-d897-4ae4-8c57-31c229e3902d'	System	26 Apr 2021 18:30:59
User entered 'No (N)'	System	26 Apr 2021 18:30:59

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

Have you been exposed to someone with 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 (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-04-26T11:30:51-07:00', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'fabf6e90-d897-4ae4-8c57-31c229e3902d'	System	26 Apr 2021 18:30:59
User entered 'No (N)'	System	26 Apr 2021 18:30:59

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-04-26T11:30:55-07:00', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'fabf6e90-d897-4ae4-8c57-31c229e3902d'	System	26 Apr 2021 18:30:59
User entered '26 Apr 2021 11:30:55'	System	26 Apr 2021 18:30:59

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 11:09:32



**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[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 (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-05-02T00:02:38-07:00', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '6c799659-414c-4bf6-b1a3-d8b270604ca2'	System	02 May 2021 07:02:52
User entered 'No (N)'	System	02 May 2021 07:02:52

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Have you been exposed to someone with 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 (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-05-02T00:02:43-07:00', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '6c799659-414c-4bf6-b1a3-d8b270604ca2'	System	02 May 2021 07:02:52
User entered 'No (N)'	System	02 May 2021 07:02:52

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-05-02T00:02:47-07:00', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: '6c799659-414c-4bf6-b1a3-d8b270604ca2'	System	02 May 2021 07:02:52
User entered '02 May 2021 00:02:47'	System	02 May 2021 07:02:52

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 11:09:32



**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 11:09:32



**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 11:09:32



**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 11:09:32



**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 11:09:32



**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 11:09:32



**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 11:09:32



**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 11:09:32



**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 11:09:32



**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 11:09:32



**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 11:09:32



**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 11:09:32



**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 11:09:32



**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 11:09:32



**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 11:09:32



**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 11:09:32



**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 11:09:32



**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 11:09:32



**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 11:09:32



**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 11:09:32



**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 11:09:32



**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 11:09:32



**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 11:09:32



**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 11:09:32



**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 11:09:32



**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 11:09:32



**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 11:09:32



**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 11:09:32



**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 11:09:32

**US3162037**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:27:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:09:32
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 11:09:32

US3162037

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:27:33

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 17:36:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-02-27T12:04:38-08:00', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'e62555aa-fea3-41a6-b560-d51d1e662772'	System	27 Feb 2021 20:04:49
User entered 'No (N)'	System	27 Feb 2021 20:04:49

**US3162037**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 15:27:33**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:36:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A8C71023-4D28-4149-9763-6DEDD6139262)', Time: '2021-02-27T12:04:45-08:00', User OID: 'PatientReportedOutcome (US3162037)', ODM File OID: 'e62555aa-fea3-41a6-b560-d51d1e662772' User entered '27 Feb 2021 20:04:45'	System	27 Feb 2021 20:04:49
	System	27 Feb 2021 20:04:49

US3162037

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:27:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'Yes (Y)'	Jessica Fisher (b) (4)	25 Oct 2020 03:13:29

US3162037

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:27:33

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered '23 Oct 2020'	Jessica Fisher (b) (4)	25 Oct 2020 03:13:29



**US3162037**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:27:33**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'Contact Made (CONTACT MADE)'	Jessica Fisher (b) (4)	25 Oct 2020 03:13:29

US3162037

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:27:33

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4)	13 Feb 2021 01:35:19
	(b) (4)	
User entered empty.	Jessica Fisher (b) (4)	25 Oct 2020 03:13:29

US3162037

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:27:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:35:19
User entered 'Yes (Y)'	Jessica Fisher (b) (4)	25 Oct 2020 03:13:37

**US3162037**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:27:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:04:44
User entered 'I'	System	25 Oct 2020 03:13:37

**US3162037**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:27:33**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:40:12
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Dec 2020 00:56:28

**US3162037**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:27:33**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:40:12
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered '25 Nov 2020'	(b) (4), (b) (6)	01 Dec 2020 00:56:28

**US3162037**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:27:33**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:40:12
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	01 Dec 2020 00:56:28

US3162037

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:27:33

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:40:12
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered empty.	(b) (4), (b) (6)	01 Dec 2020 00:56:28



US3162037

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:27:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:40:12
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Dec 2020 00:56:33

**US3162037**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:27:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:40:12
User entered 'I'	System	01 Dec 2020 00:56:33

**US3162037**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:27:33**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:40:12
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	31 Dec 2020 23:48:28

US3162037

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:27:33

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:40:12
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered '23 Dec 2020'	Tiffany Williams (b) (4) (b) (4)	31 Dec 2020 23:48:28

**US3162037**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:27:33**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:40:12
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'Contact Made (CONTACT MADE)'	Tiffany Williams (b) (4) (b) (4)	31 Dec 2020 23:48:28

US3162037

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:27:33

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:40:12
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered empty.	Tiffany Williams (b) (4) (b) (4)	31 Dec 2020 23:48:28

US3162037

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:27:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:40:12
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	31 Dec 2020 23:48:32

**US3162037**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:27:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:40:12
User entered 'I'	System	31 Dec 2020 23:48:32



US3162037

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:27:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:40:12
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	29 Jan 2021 00:19:33

US3162037

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:27:33

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:40:12
User signature succeeded.	Judith Kirstein (b) (4)	13 Feb 2021 01:34:22
	(b) (4)	
User entered '25 Jan 2021'	Tiffany Williams (b) (4)	29 Jan 2021 00:19:33
	(b) (4)	

**US3162037**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:27:33**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:40:12
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'Contact Made (CONTACT MADE)'	Tiffany Williams (b) (4) (b) (4)	29 Jan 2021 00:19:33

US3162037

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:27:33

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:40:12
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered empty.	Tiffany Williams (b) (4) (b) (4)	29 Jan 2021 00:19:33

US3162037

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:27:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:40:12
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	29 Jan 2021 00:19:38

**US3162037**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:27:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:40:12
User entered 'I'	System	29 Jan 2021 00:19:38

US3162037

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:27:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:42
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	01 Mar 2021 17:43:50

US3162037

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:27:33

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:42
User entered '25 Feb 2021'	Tiffany Williams (b) (4) (b) (4)	01 Mar 2021 17:43:50



**US3162037**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:27:33**

[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 17:18:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:42
User entered 'Clinic (Clinic)'	Tiffany Williams (b) (4) (b) (4)	01 Mar 2021 17:43:50

**US3162037**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:27:33**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:54
User entered 'VISIT4'	System	01 Mar 2021 17:43:50

US3162037

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:42
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	30 Mar 2021 03:32:24

US3162037

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:42
User entered empty.	Judith Kirstein (b) (4) (b) (4)	30 Mar 2021 03:32:24

**US3162037**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:27:33**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:42
User entered empty.	Judith Kirstein (b) (4) (b) (4)	30 Mar 2021 03:32:24

**US3162037**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:27:33**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:54
User entered empty.	System	30 Mar 2021 03:32:24

US3162037

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:42
User entered empty.	Judith Kirstein (b) (4) (b) (4)	30 Mar 2021 03:32:24

US3162037

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:42
User entered empty.	Judith Kirstein (b) (4) (b) (4)	30 Mar 2021 03:32:24



US3162037

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:42
User entered empty.	Judith Kirstein (b) (4) (b) (4)	30 Mar 2021 03:32:24

US3162037

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:42
User entered empty.	Judith Kirstein (b) (4) (b) (4)	30 Mar 2021 03:32:24

**US3162037**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:27:33**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:54
User entered empty.	System	30 Mar 2021 03:32:24

US3162037

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:42
User entered empty.	Judith Kirstein (b) (4) (b) (4)	30 Mar 2021 03:32:24

US3162037

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:54
User entered empty.	System	30 Mar 2021 03:32:24

US3162037

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:42
User entered empty.	Judith Kirstein (b) (4) (b) (4)	30 Mar 2021 03:32:24

**US3162037**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:27:33**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:54
User entered empty.	System	30 Mar 2021 03:32:24

US3162037

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:42
User entered empty.	Judith Kirstein (b) (4) (b) (4)	30 Mar 2021 03:32:24



**US3162037**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:27:33**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:54
User entered empty.	System	30 Mar 2021 03:32:24

US3162037

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:33

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:54

**US3162037**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:27:33**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:54

US3162037

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:27:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:42
User entered 'No (N)'	Tiffany Williams (b) (4) (b) (4)	01 Mar 2021 17:44:00

US3162037

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:27:33

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:42
User entered empty.	Tiffany Williams (b) (4) (b) (4)	01 Mar 2021 17:44:00

US3162037

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:27:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:42
User entered 'Yes (Y)' reason for change: New Information	Tiffany Williams (b) (4) (b) (4)	05 Mar 2021 00:09:09
User entered 'No (N)'	Tiffany Williams (b) (4) (b) (4)	01 Mar 2021 17:44:23

US3162037

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:27:33

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:42
User entered '25 Feb 2021' reason for change: New Information	Tiffany Williams (b) (4) (b) (4)	05 Mar 2021 00:09:09
User entered empty.	Tiffany Williams (b) (4) (b) (4)	01 Mar 2021 17:44:23

US3162037

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:27:33

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:42
User entered '09:50' reason for change: New Information	Tiffany Williams (b) (4) (b) (4)	05 Mar 2021 00:09:09
User entered empty.	Tiffany Williams (b) (4) (b) (4)	01 Mar 2021 17:44:23



**US3162037**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:27:33**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:54
User entered '25 Feb 2021 09:50'	System	05 Mar 2021 00:09:09
User entered empty.	System	01 Mar 2021 17:44:23

US3162037

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:27:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:42
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	01 Mar 2021 17:44:29

**US3162037**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:27:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:18:54
User entered 'I'	System	01 Mar 2021 17:44:29

US3162037

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:27:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	16 Apr 2021 17:17:47

US3162037

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:27:33

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered '26 Mar 2021'	(b) (4), (b) (6)	16 Apr 2021 17:17:47

US3162037

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:27:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	16 Apr 2021 17:17:47

**US3162037**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:27:33**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 17:17:47

US3162037

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:27:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Apr 2021 17:18:03



**US3162037**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:27:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Apr 2021 17:18:03

**US3162037**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:27:33**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	25 Feb 2021 22:06:20

**US3162037**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:27:33**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered '25 Feb 2021'	Tiffany Williams (b) (4) (b) (4)	25 Feb 2021 22:06:20

US3162037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:27:33

[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 07:36:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered 'Clinic (Clinic)'	Tiffany Williams (b) (4) (b) (4)	25 Feb 2021 22:06:20

**US3162037**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:27:33**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User entered 'UNBLND_DECIDE'	System	25 Feb 2021 22:06:20

US3162037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:27:33

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 22:50:13
	(b) (4)	
User entered '25 Feb 2021'	Tiffany Williams (b) (4)	25 Feb 2021 22:07:02
	(b) (4)	

**US3162037**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:27:33**

[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 07:36:58
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 22:50:13
	(b) (4)	
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 02:10:23

US3162037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:27:33

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	25 Feb 2021 22:07:02



**US3162037**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:27:33**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 22:50:13
	(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 02:10:23

US3162037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:27:33

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered '25 Feb 2021'	Tiffany Williams (b) (4) (b) (4)	25 Feb 2021 22:07:02

US3162037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:27:33

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered 'Placebo (Placebo)'	Tiffany Williams (b) (4) (b) (4)	25 Feb 2021 22:07:02

**US3162037**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:27:33**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered 'Placebo (Placebo)'	Tiffany Williams (b) (4) (b) (4)	25 Feb 2021 22:07:02

**US3162037**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:27:33**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered 'Placebo (Placebo)'	Tiffany Williams (b) (4) (b) (4)	25 Feb 2021 22:07:02

US3162037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:27:33

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	25 Feb 2021 22:07:02

**US3162037**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:27:33**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User entered '1'	System	25 Feb 2021 22:07:02

**US3162037**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:27:33**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User entered 'I'	System	25 Feb 2021 22:07:02



US3162037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:27:33

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered '69' in	Tiffany Williams (b) (4) (b) (4)	25 Feb 2021 22:14:03

US3162037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:27:33

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered '177.1' lb	Tiffany Williams (b) (4) (b) (4)	25 Feb 2021 22:14:03

US3162037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:27:33

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User entered '26.20778'	System	25 Feb 2021 22:14:03
DataPoint set to visible.	System	25 Feb 2021 22:07:02

US3162037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:27:33

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered '69' in	Tiffany Williams (b) (4) (b) (4)	25 Feb 2021 22:14:03

US3162037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:27:33

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered '177.1' lb	Tiffany Williams (b) (4) (b) (4)	25 Feb 2021 22:14:03

US3162037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:27:33

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User entered '26.20778'	System	25 Feb 2021 22:14:03
DataPoint set to visible.	System	25 Feb 2021 22:07:02

US3162037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User accepted default value 'Pre-Dose (PREDOSE)'	Tiffany Williams (b) (4) (b) (4)	25 Feb 2021 22:14:03

US3162037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User closed query 'Per CDM: Visit 4 Day 209 and Participant Decision Visit / OL-D1 are both dated 25Feb2021. However, the data on the Vital signs forms in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 12:01:12
Query 'Per CDM: Visit 4 Day 209 and Participant Decision Visit / OL-D1 are both dated 25Feb2021. However, the data on the Vital signs forms in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile.' answered with 'Reconciled' (Site from DM).	Judith Kirstein (b) (4) (b) (4)	30 Mar 2021 03:32:09
User opened query 'Per CDM: Visit 4 Day 209 and Participant Decision Visit / OL-D1 are both dated 25Feb2021. However, the data on the Vital signs forms in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 20:19:56
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	25 Feb 2021 22:14:03



US3162037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered '25 Feb 2021'	Tiffany Williams (b) (4) (b) (4)	25 Feb 2021 22:14:03

US3162037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered '11:24'	Tiffany Williams (b) (4) (b) (4)	25 Feb 2021 22:14:03

**US3162037**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:27:33**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User entered '25 Feb 2021 11:24'	System	25 Feb 2021 22:14:03

US3162037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered '98.2' F	Tiffany Williams (b) (4) (b) (4)	25 Feb 2021 22:14:03

US3162037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered 'Oral (Oral)'	Tiffany Williams (b) (4) (b) (4)	25 Feb 2021 22:14:03

US3162037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered empty.	Tiffany Williams (b) (4) (b) (4)	25 Feb 2021 22:14:03

US3162037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered '64'	Tiffany Williams (b) (4) (b) (4)	25 Feb 2021 22:14:03

**US3162037**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:27:33**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User entered 'bpm'	System	25 Feb 2021 22:14:03



US3162037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered '12'	Tiffany Williams (b) (4) (b) (4)	25 Feb 2021 22:14:03

US3162037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User entered 'breaths/min'	System	25 Feb 2021 22:14:03

US3162037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered '108'	Tiffany Williams (b) (4) (b) (4)	25 Feb 2021 22:14:03

US3162037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User entered 'mmHg'	System	25 Feb 2021 22:14:03

US3162037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
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)	26 Feb 2021 16:41:30
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 'PER SOURCE' (Site from System).	Tiffany Williams (b) (4) (b) (4)	25 Feb 2021 22:15:57
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		25 Feb 2021 22:14:03
User entered '54'	Tiffany Williams (b) (4) (b) (4)	25 Feb 2021 22:14:03

**US3162037**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:27:33**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User entered 'mmHg'	System	25 Feb 2021 22:14:03

US3162037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:27:33

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 22:50:13
	(b) (4)	
User entered '69' in	Tiffany Williams (b) (4)	25 Feb 2021 22:14:03
	(b) (4)	

US3162037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:27:33

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered '177.1' lb	Tiffany Williams (b) (4) (b) (4)	25 Feb 2021 22:14:03



US3162037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:27:33

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User entered '26.20778'	System	25 Feb 2021 22:14:03
DataPoint set to visible.	System	25 Feb 2021 22:07:02

US3162037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User accepted default value 'Post-Dose (POSTDOSE)'	Tiffany Williams (b) (4) (b) (4)	25 Feb 2021 22:14:03

US3162037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	25 Feb 2021 22:14:03

US3162037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered '25 Feb 2021'	Tiffany Williams (b) (4) (b) (4)	25 Feb 2021 22:14:03

US3162037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered '12:40'	Tiffany Williams (b) (4) (b) (4)	25 Feb 2021 22:14:03

**US3162037**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:27:33**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User entered '25 Feb 2021 12:40'	System	25 Feb 2021 22:14:03

US3162037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered '98.8' F	Tiffany Williams (b) (4) (b) (4)	25 Feb 2021 22:14:03

US3162037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered 'Oral (Oral)'	Tiffany Williams (b) (4) (b) (4)	25 Feb 2021 22:14:03



US3162037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered empty.	Tiffany Williams (b) (4) (b) (4)	25 Feb 2021 22:14:03

**US3162037**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:27:33**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered '50'	Tiffany Williams (b) (4) (b) (4)	25 Feb 2021 22:14:03

**US3162037**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:27:33**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User entered 'bpm'	System	25 Feb 2021 22:14:03

US3162037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered '13'	Tiffany Williams (b) (4) (b) (4)	25 Feb 2021 22:14:03

US3162037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User entered 'breaths/min'	System	25 Feb 2021 22:14:03

US3162037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered '121'	Tiffany Williams (b) (4) (b) (4)	25 Feb 2021 22:14:03

US3162037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User entered 'mmHg'	System	25 Feb 2021 22:14:03

US3162037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
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)	26 Feb 2021 16:41:34
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 'PER SOURCE' (Site from System).	Tiffany Williams (b) (4) (b) (4)	25 Feb 2021 22:19:46
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		25 Feb 2021 22:14:03
User entered '57'	Tiffany Williams (b) (4) (b) (4)	25 Feb 2021 22:14:03



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User entered 'mmHg'	System	25 Feb 2021 22:14:03

US3162037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:27:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered 'No (N)'	Tiffany Williams (b) (4) (b) (4)	25 Feb 2021 22:07:14

US3162037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:27:33

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered empty.	Tiffany Williams (b) (4) (b) (4)	25 Feb 2021 22:07:14

US3162037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:27:33

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	25 Feb 2021 22:07:39

US3162037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:27:33

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered empty.	Tiffany Williams (b) (4) (b) (4)	25 Feb 2021 22:07:39

US3162037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:27:33

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered empty.	Tiffany Williams (b) (4) (b) (4)	25 Feb 2021 22:07:39

US3162037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:27:33

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User entered 'mRNA-1273'	System	25 Feb 2021 22:07:39
DataPoint set to visible.	System	25 Feb 2021 22:07:02

US3162037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:27:33

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered '25 Feb 2021'	Tiffany Williams (b) (4) (b) (4)	25 Feb 2021 22:07:39



US3162037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:27:33

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered '12:05'	Tiffany Williams (b) (4) (b) (4)	25 Feb 2021 22:07:39

**US3162037**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:27:33**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User entered '25 Feb 2021 12:05'	System	25 Feb 2021 22:07:39

US3162037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:27:33

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered 'Left Arm (LEFT ARM)'	Tiffany Williams (b) (4) (b) (4)	25 Feb 2021 22:07:39

US3162037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:27:33

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User entered 'ONCE'	System	25 Feb 2021 22:07:39

US3162037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:27:33

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User entered 'INTRAMUSCULAR'	System	25 Feb 2021 22:07:39

US3162037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:27:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	25 Feb 2021 22:07:57

US3162037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:27:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered '25 Feb 2021'	Tiffany Williams (b) (4) (b) (4)	25 Feb 2021 22:07:57

US3162037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:27:33

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered '09:50'	Tiffany Williams (b) (4) (b) (4)	25 Feb 2021 22:07:57



**US3162037**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:27:33**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User entered '25 Feb 2021 09:50'	System	25 Feb 2021 22:07:57

US3162037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:27:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	25 Feb 2021 22:08:20

US3162037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:27:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered '25 Feb 2021'	Tiffany Williams (b) (4) (b) (4)	25 Feb 2021 22:08:20

**US3162037**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 15:27:33**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered '09:47'	Tiffany Williams (b) (4) (b) (4)	25 Feb 2021 22:08:20

**US3162037**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 15:27:33**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User entered '25 Feb 2021 09:47'	System	25 Feb 2021 22:08:20

US3162037

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:27:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	25 Feb 2021 22:08:42

**US3162037**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:27:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:36:58
User entered 'I'	System	25 Feb 2021 22:08:42

**US3162037**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:27:33**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:48:00
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 22:50:42
	(b) (4)	
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	08 Mar 2021 16:54:44
	(b) (4)	



**US3162037**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:27:33**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:48:00
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 22:50:42
	(b) (4)	
User entered '4 Mar 2021'	Tiffany Williams (b) (4)	08 Mar 2021 16:54:44
	(b) (4)	

**US3162037**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:27:33**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:48:00
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:42
User entered 'Contact Made (CONTACT MADE)'	Tiffany Williams (b) (4) (b) (4)	08 Mar 2021 16:54:44

US3162037

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:27:33

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:48:00
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 22:50:42
	(b) (4)	
User entered empty.	Tiffany Williams (b) (4)	08 Mar 2021 16:54:44
	(b) (4)	

**US3162037**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:27:33**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:48:00
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 22:50:13
	(b) (4)	
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	08 Mar 2021 16:54:59
	(b) (4)	

**US3162037**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:27:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:48:00
User entered 'I'	System	08 Mar 2021 16:54:59

**US3162037**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:27:33**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:48:00
User entered '1'	System	08 Mar 2021 16:54:59
DataPoint set to visible.	System	08 Mar 2021 16:54:59

**US3162037**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:27:33**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:06:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	26 Mar 2021 21:09:32

**US3162037**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:27:33**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:06:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered '26 Mar 2021'	Tiffany Williams (b) (4) (b) (4)	26 Mar 2021 21:09:32



**US3162037**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:27:33**

[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 07:06:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered 'Clinic (Clinic)'	Tiffany Williams (b) (4) (b) (4)	26 Mar 2021 21:09:32

**US3162037**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:27:33**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:06:52
User entered 'OLD29'	System	26 Mar 2021 21:09:32

US3162037

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:06:52
User accepted default value 'Pre-Dose (PREDOSE)'		29 Mar 2021 20:50:31

US3162037

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:06:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Mar 2021 20:50:31

**US3162037**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:27:33**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:06:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered '26 Mar 2021'	(b) (4), (b) (6)	29 Mar 2021 20:50:31

**US3162037**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:27:33**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:06:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered '12:18'	(b) (4), (b) (6)	29 Mar 2021 20:50:31

**US3162037**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:27:33**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:06:52
User entered '26 Mar 2021 12:18'	System	29 Mar 2021 20:50:31

US3162037

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:06:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered '98.3' F	(b) (4), (b) (6)	29 Mar 2021 20:50:31



US3162037

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:06:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered 'Oral (Oral)'	(b) (4), (b) (6)	29 Mar 2021 20:50:31

US3162037

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:06:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 20:50:31

**US3162037**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:27:33**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:06:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered '55'	(b) (4), (b) (6)	29 Mar 2021 20:50:31

**US3162037**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:27:33**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:06:52
User entered 'bpm'	System	29 Mar 2021 20:50:31

US3162037

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:06:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered '15'	(b) (4), (b) (6)	29 Mar 2021 20:50:31

US3162037

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:06:52
User entered 'breaths/min'	System	29 Mar 2021 20:50:31

US3162037

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:06:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered '124'	(b) (4), (b) (6)	29 Mar 2021 20:50:31

**US3162037**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:27:33**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:06:52
User entered 'mmHg'	System	29 Mar 2021 20:50:31



US3162037

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:27:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:06:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered '71'	(b) (4), (b) (6)	29 Mar 2021 20:50:31

**US3162037**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:27:33**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:06:52
User entered 'mmHg'	System	29 Mar 2021 20:50:31

US3162037

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:06:52
User accepted default value 'Post-Dose (POSTDOSE)'		29 Mar 2021 20:50:31

US3162037

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:06:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Mar 2021 20:50:31

US3162037

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:06:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered '26 Mar 2021'	(b) (4), (b) (6)	29 Mar 2021 20:50:31

US3162037

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:06:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered '13:36'	(b) (4), (b) (6)	29 Mar 2021 20:50:31

**US3162037**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:27:33**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:06:52
User entered '26 Mar 2021 13:36'	System	29 Mar 2021 20:50:31

US3162037

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:06:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered '98.9' F	(b) (4), (b) (6)	29 Mar 2021 20:50:31



**US3162037**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:27:33**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:06:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered 'Oral (Oral)'	(b) (4), (b) (6)	29 Mar 2021 20:50:31

US3162037

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:06:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 20:50:31

**US3162037**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:27:33**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:06:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered '55'	(b) (4), (b) (6)	29 Mar 2021 20:50:31

**US3162037**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:27:33**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:06:52
User entered 'bpm'	System	29 Mar 2021 20:50:31

US3162037

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:06:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered '13'	(b) (4), (b) (6)	29 Mar 2021 20:50:31

**US3162037**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:27:33**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:06:52
User entered 'breaths/min'	System	29 Mar 2021 20:50:31

US3162037

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:06:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered '100'	(b) (4), (b) (6)	29 Mar 2021 20:50:31

**US3162037**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:27:33**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:06:52
User entered 'mmHg'	System	29 Mar 2021 20:50:31



US3162037

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:27:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:06:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered '60'	(b) (4), (b) (6)	29 Mar 2021 20:50:31

**US3162037**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:27:33**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:06:52
User entered 'mmHg'	System	29 Mar 2021 20:50:31

US3162037

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:27:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:06:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered 'No (N)'	(b) (4), (b) (6)	29 Mar 2021 20:50:39

US3162037

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:27:33

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:06:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 20:50:39

US3162037

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:27:33

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:06:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	26 Mar 2021 21:09:50

US3162037

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:27:33

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:06:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered empty.	Tiffany Williams (b) (4) (b) (4)	26 Mar 2021 21:09:50

US3162037

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:27:33

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:06:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered empty.	Tiffany Williams (b) (4) (b) (4)	26 Mar 2021 21:09:50

US3162037

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:27:33

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:06:52
User entered 'mRNA-1273'	System	26 Mar 2021 21:09:50
DataPoint set to visible.	System	08 Mar 2021 16:54:59



US3162037

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:27:33

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:06:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered '26 Mar 2021'	Tiffany Williams (b) (4) (b) (4)	26 Mar 2021 21:09:50

US3162037

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:27:33

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:06:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered '13:01'	Tiffany Williams (b) (4) (b) (4)	26 Mar 2021 21:09:50

**US3162037**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:27:33**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:06:52
User entered '26 Mar 2021 13:01'	System	26 Mar 2021 21:09:50

US3162037

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:27:33

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:06:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered 'Left Arm (LEFT ARM)'	Tiffany Williams (b) (4) (b) (4)	26 Mar 2021 21:09:50

US3162037

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:27:33

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:06:52
User entered 'ONCE'	System	26 Mar 2021 21:09:50

US3162037

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:27:33

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:06:52
User entered 'INTRAMUSCULAR'	System	26 Mar 2021 21:09:50

US3162037

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:27:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:06:52
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	26 Mar 2021 21:09:56

**US3162037**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:27:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:06:52
User entered 'I'	System	26 Mar 2021 21:09:56



**US3162037**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:27:33**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Apr 2021 19:19:47

**US3162037**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:27:33**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered '02 Apr 2021'	(b) (4), (b) (6)	05 Apr 2021 19:19:47

**US3162037**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:27:33**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	05 Apr 2021 19:19:47

**US3162037**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:27:33**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 19:19:47

US3162037

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:27:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Apr 2021 19:19:56

**US3162037**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:27:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Apr 2021 19:19:56

US3162037

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:27:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	03 May 2021 18:47:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 May 2021 18:33:22

**US3162037**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:27:33**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	03 May 2021 18:47:16
User entered '30 Apr 2021'	(b) (4), (b) (6)	03 May 2021 18:33:22



US3162037

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:27:33

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	03 May 2021 18:47:16
User entered 'Clinic (Clinic)'	(b) (4), (b) (6) (b) (4)	03 May 2021 18:33:22

**US3162037**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:27:33**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	03 May 2021 18:33:22

US3162037

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	03 May 2021 18:47:16
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 18:33:32

US3162037

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	03 May 2021 18:47:16
User entered empty.	(b) (4), (b) (6)	03 May 2021 18:33:32

**US3162037**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:27:33**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	03 May 2021 18:47:16
User entered empty.	(b) (4), (b) (6)	03 May 2021 18:33:32

**US3162037**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:27:33**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 18:33:32

US3162037

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:33

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	03 May 2021 18:47:16
User entered empty.	(b) (4), (b) (6)	03 May 2021 18:33:32

US3162037

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:33

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	03 May 2021 18:47:16
User entered empty.	(b) (4), (b) (6)	03 May 2021 18:33:32



**US3162037**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:27:33**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	03 May 2021 18:47:16
User entered empty.	(b) (4), (b) (6)	03 May 2021 18:33:32

US3162037

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	03 May 2021 18:47:16
User entered empty.	(b) (4), (b) (6)	03 May 2021 18:33:32

**US3162037**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:27:33**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 18:33:32

US3162037

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	03 May 2021 18:47:16
User entered empty.	(b) (4), (b) (6)	03 May 2021 18:33:32

**US3162037**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:27:33**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 18:33:32

US3162037

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	03 May 2021 18:47:16
User entered empty.	(b) (4), (b) (6)	03 May 2021 18:33:32

**US3162037**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:27:33**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 18:33:32

US3162037

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:27:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	03 May 2021 18:47:16
User entered empty.	(b) (4), (b) (6)	03 May 2021 18:33:32



**US3162037**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:27:33**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 18:33:32

US3162037

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:27:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	03 May 2021 18:47:16
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 18:33:39

US3162037

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:27:33

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	03 May 2021 18:47:16
User entered empty.	(b) (4), (b) (6)	03 May 2021 18:33:39

US3162037

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:27:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	03 May 2021 18:47:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 May 2021 18:33:53

US3162037

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:27:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	03 May 2021 18:47:16
User entered '30 Apr 2021'	(b) (4), (b) (6) (b) (4)	03 May 2021 18:33:53

US3162037

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:27:33

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	03 May 2021 18:47:16
User entered '12:35'	(b) (4), (b) (6)	03 May 2021 18:33:53

**US3162037**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:27:33**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '30 Apr 2021 12:35'	System	03 May 2021 18:33:53

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 09 Jun 2021 15:27:33**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:03:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'Yes (Y)' reason for change: New Information	Jared Bradshaw (b) (4) (b) (4)	22 Aug 2020 02:12:31
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:08:51



**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:27:33**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:53

US3162037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:27:33

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User closed query 'Per DM CLR: Please review this Solicited Adverse Reaction as this has been recorded in the diary forms. Please review and remove if needed. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 17:36:37
Query 'Per DM CLR: Please review this Solicited Adverse Reaction as this has been recorded in the diary forms. Please review and remove if needed. Else, clarify.' answered with 'THIS HEADACHE OCCURRED ON DAY 8 WHICH QUALIFIES IT TO BE AN AE. I REALIZE SHE DID NOT RECORD IT IN HER DIARY, BUT IT OCCURRED ON THE DAY I CALLED HER FOR DAY 8 PHONE CALL SO IT SHOULD REMAIN AS AE, AND NOT SOLICITED' (Site from DM).	Judith Kirstein (b) (4) (b) (4)	24 Sep 2020 00:43:26
User opened query 'Per DM CLR: Please review this Solicited Adverse Reaction as this has been recorded in the diary forms. Please review and remove if needed. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 05:09:23
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) (b) (4)	22 Aug 2020 02:15:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Aug 2020 02:15:25
Data point term sent to Coder	System	22 Aug 2020 02:14:44
User entered 'Headache'	Jared Bradshaw (b) (4) (b) (4)	22 Aug 2020 02:14:23

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:27:33**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	22 Aug 2020 02:14:23

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:27:33**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	22 Aug 2020 02:14:23

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:27:33**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	22 Aug 2020 02:14:23

US3162037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:27:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
Query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' canceled (Site from System).	(b) (4), (b) (6)	11 Sep 2020 16:30:40
User opened query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	28 Aug 2020 20:58:14
User entered '07 Aug 2020'	Jared Bradshaw (b) (4) (b) (4)	22 Aug 2020 02:14:23

US3162037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:27:33

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	07 Sep 2020 17:48:17
User entered empty; reason for change Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	07 Sep 2020 17:48:17
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	03 Sep 2020 22:59:51
User entered '02:00' reason for change: Data Entry Error	Jourdan Manfred (b) (4) (b) (4)	03 Sep 2020 22:59:51
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	24 Aug 2020 14:52:01
User entered empty; reason for change Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	24 Aug 2020 14:52:01
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	22 Aug 2020 02:14:23
User entered '02:00'	Jared Bradshaw (b) (4) (b) (4)	22 Aug 2020 02:14:23

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:27:33**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:53
User entered empty.	System	07 Sep 2020 17:48:17
User entered '07 Aug 2020 02:00'	System	03 Sep 2020 22:59:51
User entered empty.	System	24 Aug 2020 14:52:01
User entered '07 Aug 2020 02:00'	System	22 Aug 2020 02:14:23



**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:27:33**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	22 Aug 2020 02:14:23

US3162037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:27:33

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered '07 Aug 2020'	Jared Bradshaw (b) (4) (b) (4)	22 Aug 2020 02:14:23

US3162037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:27:33

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	07 Sep 2020 17:48:17
User entered empty; reason for change Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	07 Sep 2020 17:48:17
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	03 Sep 2020 22:59:51
User entered '07:30' reason for change: Data Entry Error	Jourdan Manfred (b) (4) (b) (4)	03 Sep 2020 22:59:51
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	24 Aug 2020 14:52:16
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	24 Aug 2020 14:52:16
User entered empty; reason for change Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	24 Aug 2020 14:52:16
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	24 Aug 2020 14:52:01
User entered '0:' (non-conformant).	Cynthia Kunakom (b) (4) (b) (4)	24 Aug 2020 14:52:01
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	22 Aug 2020 02:14:23
User entered '07:30'	Jared Bradshaw (b) (4) (b) (4)	22 Aug 2020 02:14:23

US3162037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:27:33

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:53
User entered empty.	System	07 Sep 2020 17:48:17
User entered '07 Aug 2020 07:30'	System	03 Sep 2020 22:59:51
User entered empty.	System	24 Aug 2020 14:52:16
User entered '07 Aug 2020 0:' (non-conformant).	System	24 Aug 2020 14:52:01
User entered '07 Aug 2020 07:30'	System	22 Aug 2020 02:14:23

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:27:33**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jared Bradshaw (b) (4) (b) (4)	22 Aug 2020 02:14:23

US3162037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:27:33

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	22 Aug 2020 02:14:23

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:27:33**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	22 Aug 2020 02:14:23

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:27:33**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	22 Aug 2020 02:14:23



US3162037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:27:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	22 Aug 2020 02:14:23

US3162037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:27:33

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	22 Aug 2020 02:14:23

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:27:33**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	22 Aug 2020 02:14:23

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:27:33**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	22 Aug 2020 02:14:23

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:27:33**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	22 Aug 2020 02:14:23

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:27:33**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	22 Aug 2020 02:14:23

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:27:33**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	22 Aug 2020 02:14:23

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:27:33**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	22 Aug 2020 02:14:23



US3162037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:27:33

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered 'Not Related (NOT RELATED)'	Jared Bradshaw (b) (4) (b) (4)	22 Aug 2020 02:14:23

US3162037

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:27:33

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered 'Not Related (NOT RELATED)'	Jared Bradshaw (b) (4) (b) (4)	22 Aug 2020 02:14:23

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:27:33**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered 'None (NONE)'	Jared Bradshaw (b) (4) (b) (4)	22 Aug 2020 02:14:23

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:27:33**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	22 Aug 2020 02:14:23

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:27:33**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered 'I'	Jared Bradshaw (b) (4) (b) (4)	22 Aug 2020 02:14:23

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:27:33**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	22 Aug 2020 02:14:23

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:27:33**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jared Bradshaw (b) (4) (b) (4)	22 Aug 2020 02:14:23

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:27:33**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	22 Aug 2020 02:14:23



**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:27:33**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	22 Aug 2020 02:14:23

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:27:33**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:53
User entered '0'	System	22 Aug 2020 02:14:23

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:27:33**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:53
User entered '0'	System	22 Aug 2020 02:14:23

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:27:33**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:53

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:27:33**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:58

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:27:33

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
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: Musculoskeletal pain, LLT: Shoulder pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 15:15:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 15:15:35
Data point term sent to Coder	System	31 Aug 2020 15:14:54
User entered 'Left shoulder pain'	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:14:25

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:27:33**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:14:25

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:27:33**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:14:25



**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:27:33**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:14:25

US3162037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:27:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
Query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' canceled (Site from System).	(b) (4), (b) (6)	11 Sep 2020 16:30:49
User opened query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	31 Aug 2020 15:14:25
User entered '23 Aug 2020'	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:14:25

US3162037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:27:33

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	07 Sep 2020 17:48:38
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	07 Sep 2020 17:48:38
User entered empty; reason for change Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	07 Sep 2020 17:48:38
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	03 Sep 2020 23:00:47
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	03 Sep 2020 23:00:47
User entered 'UN:UN' (non-conformant).	Jourdan Manfred (b) (4) (b) (4)	03 Sep 2020 23:00:47
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:14:25

US3162037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:27:33

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:58
User entered empty.	System	07 Sep 2020 17:48:38
User entered '23 Aug 2020 UN:UN' (non-conformant).	System	03 Sep 2020 23:00:47
User entered empty.	System	31 Aug 2020 15:14:25

US3162037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:27:33

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered 'No (N)' reason for change: New Information	Jessica Fisher (b) (4)	27 Mar 2021 03:30:51
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT".' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 20:02:29
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT".' answered with 'Per phone call on 25Nov20, the pain is ongoing but improving' (Site from DM).	Judith Kirstein (b) (4) (b) (4)	25 Nov 2020 23:31:14
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT".' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 05:29:37
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:14:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:27:33

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered '15 Jan 2021' reason for change: New Information	Jessica Fisher (b) (4)	27 Mar 2021 03:30:51
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:14:25

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:27:33**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:14:25

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:27:33**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:58
User entered empty.	System	31 Aug 2020 15:14:25



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:27:33

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:14:25

US3162037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:27:33

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:14:25

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:27:33**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:14:25

US3162037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:27:33

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:14:25

US3162037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:27:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:14:25

US3162037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:27:33

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:14:25

US3162037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:27:33

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:14:25

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:27:33**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:14:25



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:27:33

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:14:25

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:27:33**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:14:25

US3162037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:27:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:14:25

US3162037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:27:33

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:14:25

US3162037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:27:33

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered 'Not Related (NOT RELATED)'	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:14:25

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:27:33**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered 'Not Related (NOT RELATED)'	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:14:25

US3162037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:27:33

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered 'None (NONE)'	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:14:25

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:27:33**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:14:25



US3162037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:27:33

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 12:19:15
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.	Judith Kirstein (b) (4) (b) (4)	24 Sep 2020 01:21:57
' answered with 'con med added' (Site from DM). User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 05:10:27
User entered 'I'	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:14:25

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:27:33**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:14:25

US3162037

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:27:33

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Jessica Fisher (b) (4)	27 Mar 2021 03:30:51
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	25 Nov 2020 23:31:31
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Sep 2020 23:00:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 23:00:47
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Jourdan Manfred (b) (4) (b) (4)	03 Sep 2020 23:00:47
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 15:14:25
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:14:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:27:33

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:14:25

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:27:33**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:14:25

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:27:33**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:58
User entered '0'	System	31 Aug 2020 15:14:25

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:27:33**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:58
User entered '0'	System	31 Aug 2020 15:14:25

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:27:33**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:58



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:27:33

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
DataPoint Verified.	(b) (4), (b) (6)	20 Feb 2021 00:31:10
Reviewed for Safety.		16 Feb 2021 23:02:41
User entered		16 Feb 2021 23:02:38
'USA-US074-2021-mRNA-1273-P301000012'		
User entered 'New' reason for change: Data Entry		16 Feb 2021 23:02:38
Error		
User entered empty.		16 Feb 2021 20:38:34

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:27:33

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Bone disorders NEC, PT: Osteonecrosis, LLT: Avascular necrosis of bone - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Apr 2021 08:28:38
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Apr 2021 08:28:38
Data point term sent to Coder	System	20 Apr 2021 03:40:08
User closed query 'For coding purposes, please split OSTEOARTHRITIS OF LEFT HIP WITH DEVELOPING AVASCULAR NECROSIS into separate entries' (Site from System).	System	20 Apr 2021 03:39:27
Query 'For coding purposes, please split OSTEOARTHRITIS OF LEFT HIP WITH DEVELOPING AVASCULAR NECROSIS into separate entries' answered with 'Term split' (Site from System).	Judith Kirstein (b) (4) (b) (4)	20 Apr 2021 03:39:27
Data point term sent to Coder	System	20 Apr 2021 03:39:07
DataPoint Un-verified.	Judith Kirstein (b) (4) (b) (4)	20 Apr 2021 03:39:03
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	20 Apr 2021 03:39:03
User entered 'DEVELOPING AVASCULAR NECROSIS of left hip' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	20 Apr 2021 03:39:03
User opened query 'For coding purposes, please split OSTEOARTHRITIS OF LEFT HIP WITH DEVELOPING AVASCULAR NECROSIS into separate entries' (Site from System).	Coder Import (b) (4) (b) (4)	19 Apr 2021 20:02:33
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:57:12
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
Data point term sent to Coder	System	13 Apr 2021 22:31:10
DataPoint Un-verified.	Judith Kirstein (b) (4) (b) (4)	13 Apr 2021 22:30:34

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:27:33

[Adverse event](#)

Audit	User	Time (GMT)
Coding entries removed.	Judith Kirstein (b) (4) (b) (4)	13 Apr 2021 22:30:34
User entered 'OSTEOARTHRITIS OF LEFT HIP WITH DEVELOPING AVASCULAR NECROSIS' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	13 Apr 2021 22:30:34
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Bone disorders NEC, PT: Osteonecrosis, LLT: Osteonecrosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Feb 2021 23:44:03
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Feb 2021 23:44:03
DataPoint Verified.	(b) (4), (b) (6)	20 Feb 2021 00:31:10
Data point term sent to Coder	System	12 Feb 2021 17:48:46
User entered 'Osteonecrosis left hip'	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 17:47:49

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:27:33

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
DataPoint Verified.	(b) (4), (b) (6)	20 Feb 2021 00:31:10
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 17:47:49

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:27:33

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
DataPoint Verified.	(b) (4), (b) (6)	20 Feb 2021 00:31:10
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 17:47:49

US3162037

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:27:33

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
DataPoint Verified.	(b) (4), (b) (6)	20 Feb 2021 00:31:10
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 17:47:49

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:27:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:56:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User closed query 'PV Query Urgent: Thank you for confirming diagnosis was after randomization. Please update the start date to reflect the date the diagnosis was made.' (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 17:04:15
Query 'PV Query Urgent: Thank you for confirming diagnosis was after randomization. Please update the start date to reflect the date the diagnosis was made.' answered with 'Diagnosis officially made 08DEC2020 during visit with orthopedic MD' (Site from Safety).	Judith Kirstein (b) (4) (b) (4)	20 Feb 2021 19:01:16
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	20 Feb 2021 19:00:03
DataPoint Un-verified.	Judith Kirstein (b) (4) (b) (4)	20 Feb 2021 19:00:03
User entered '08 Dec 2020' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	20 Feb 2021 19:00:03
DataPoint Verified.	(b) (4), (b) (6)	20 Feb 2021 00:31:10
User closed query 'PV Query Urgent: Please confirm if the left hip pain that started prior to randomization worsened or was subsequently diagnosed as osteonecrosis after subject was randomized to study. If no, please delete event from EDC.' (Site from Safety).	(b) (4), (b) (6)	16 Feb 2021 23:02:15
User opened query 'PV Query Urgent: Thank you for confirming diagnosis was after randomization. Please update the start date to reflect the date the diagnosis was made.' (Site from Safety).		16 Feb 2021 23:01:14
Query 'PV Query Urgent: Please confirm if the left hip pain that started prior to randomization worsened or was subsequently diagnosed as osteonecrosis after subject was randomized to study. If no, please delete event from EDC.' answered with 'It was diagnosed as osteonecrosis after randomization' (Site from Safety).	Judith Kirstein (b) (4) (b) (4)	16 Feb 2021 22:53:06

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:27:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query Urgent: Please confirm if the left hip pain that started prior to randomization worsened or was subsequently diagnosed as osteonecrosis after subject was randomized to study. If no, please delete event from EDC. ' (Site from Safety).	(b) (4), (b) (6)	16 Feb 2021 20:41:14
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	12 Feb 2021 17:47:49
User entered 'UN May 2020' (non-conformant).	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 17:47:49



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:27:33

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
DataPoint Verified.	(b) (4), (b) (6)	20 Feb 2021 00:31:10
User entered empty.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 17:47:49

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:27:33**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Feb 2021 17:47:49

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:27:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
DataPoint Verified.	(b) (4), (b) (6)	20 Feb 2021 00:31:10
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 17:47:49

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:27:33

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
DataPoint Verified.	(b) (4), (b) (6)	20 Feb 2021 00:31:10
User entered '8 Feb 2021'	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 17:47:49

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:27:33

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
DataPoint Verified.	(b) (4), (b) (6)	20 Feb 2021 00:31:10
User entered empty.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 17:47:49

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:27:33**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Feb 2021 17:47:49

US3162037

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:27:33

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
DataPoint Verified.	(b) (4), (b) (6)	20 Feb 2021 00:31:10
User entered 'Grade 4 (Grade 4)'	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 17:47:49

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:27:33

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
DataPoint Verified.	(b) (4), (b) (6)	20 Feb 2021 00:31:10
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 17:47:49



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:27:33

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
DataPoint Verified.	(b) (4), (b) (6)	20 Feb 2021 00:31:10
User entered '0'	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 17:47:49

US3162037

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:27:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
DataPoint Verified.	(b) (4), (b) (6)	20 Feb 2021 00:31:10
User entered '0'	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 17:47:49

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:27:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
DataPoint Verified.	(b) (4), (b) (6)	20 Feb 2021 00:31:10
User entered 'I'	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 17:47:49

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:27:33

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
DataPoint Verified.	(b) (4), (b) (6)	20 Feb 2021 00:31:10
User entered '8 Feb 2021'	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 17:47:49

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:27:33

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User closed query 'PV Query: Please provide the reason why the subject remained hospitalized even after the event resolved. Did the subject experience another SAE?' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 19:18:18
Query 'PV Query: Please provide the reason why the subject remained hospitalized even after the event resolved. Did the subject experience another SAE?' answered with 'The event resolved on 08FEB when her hip was replaced. She stayed overnight to be monitored for safety.' (Site from Safety).	Judith Kirstein (b) (4) (b) (4)	28 Feb 2021 19:02:27
User opened query 'PV Query: Please provide the reason why the subject remained hospitalized even after the event resolved. Did the subject experience another SAE?' (Site from Safety).	(b) (4), (b) (6)	27 Feb 2021 18:11:13
DataPoint Verified.		20 Feb 2021 00:31:10
User entered '9 Feb 2021'	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 17:47:49

US3162037

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:27:33

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
DataPoint Verified.	(b) (4), (b) (6)	20 Feb 2021 00:31:10
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 17:47:49

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:27:33

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
DataPoint Verified.	(b) (4), (b) (6)	20 Feb 2021 00:31:10
User entered empty.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 17:47:49

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:27:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
DataPoint Verified.	(b) (4), (b) (6)	20 Feb 2021 00:31:10
User entered '0'	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 17:47:49



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:27:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
DataPoint Verified.	(b) (4), (b) (6)	20 Feb 2021 00:31:10
User entered '0'	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 17:47:49

US3162037

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:27:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
DataPoint Verified.	(b) (4), (b) (6)	20 Feb 2021 00:31:10
User entered '0'	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 17:47:49

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:27:33

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
DataPoint Verified.	(b) (4), (b) (6)	20 Feb 2021 00:31:10
User entered 'Not Related (NOT RELATED)'	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 17:47:49

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:27:33

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
DataPoint Verified.	(b) (4), (b) (6)	20 Feb 2021 00:31:10
User entered 'Not Related (NOT RELATED)'	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 17:47:49

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:27:33

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
DataPoint Verified.	(b) (4), (b) (6)	20 Feb 2021 00:31:10
User entered 'Not Applicable (NOT APPLICABLE)'	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 17:47:49

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:27:33

None

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
DataPoint Verified.	(b) (4), (b) (6)	20 Feb 2021 00:31:10
User entered '0'	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 17:47:49

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:27:33

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
DataPoint Verified.	(b) (4), (b) (6)	20 Feb 2021 00:31:10
User entered '0'	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 17:47:49

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:27:33

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
DataPoint Verified.	(b) (4), (b) (6)	20 Feb 2021 00:31:10
User entered 'I'	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 17:47:49



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:27:33

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
DataPoint Verified.	(b) (4), (b) (6)	20 Feb 2021 00:31:10
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 17:47:49

US3162037

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:27:33

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
DataPoint Verified.	(b) (4), (b) (6)	20 Feb 2021 00:31:10
User entered empty.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 17:47:49

US3162037

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:27:33

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 18:59:35
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 15:06:29
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. [mRNA-1273 protocols where subject was hospitalization during study participation]' (Site from Safety).		14 Apr 2021 15:06:19
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'See narrative. Do you need records to be uploaded? The query says "If needed" but her surgery was straightforward, without complications, so records won't be sent unless you request them.' (Site from Safety).	Judith Kirstein (b) (4) (b) (4)	13 Apr 2021 22:26:53
DataPoint Un-verified.	Judith Kirstein (b) (4) (b) (4)	13 Apr 2021 22:24:19

US3162037

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:27:33

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT HAD ONSET OF LEFT HIP PAIN IN MAY2020. MRI on 13NOV2020 suggested "developing avascular necrosis" of left hip. Xray of left hip on 08Jan2021 had shown moderate to advanced osteoarthritis of the left hip. Subject was ADMITTED TO HOSPITAL FOR PLANNED SURGERY ON 8FEB2021, HAD TOTAL LEFT HIP arthroplasty THAT DAY, DISCHARGED TO HOME ON 9FEB2021. Relevant lab results from 09FEB21 include: WBC 16,900 per microliter (normal 4500-10,700 per microliter, hemoglobin 9.6 grams per deciliter (normal 12.0 to 15.0 grams per deciliter), hematocrit 29% (normal 36 to 45%)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	13 Apr 2021 22:24:19
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. [mRNA-1273 protocols where subject was hospitalization during study participation]' answered with 'Per hospital record, subject did not have Covid testing during the hospital admission' (Site from Safety).	Judith Kirstein (b) (4) (b) (4)	13 Apr 2021 21:45:54
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 12:41:25
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. [mRNA-1273 protocols where subject was hospitalization during study participation]' (Site from Safety).		22 Feb 2021 12:40:54
DataPoint Verified.	(b) (4), (b) (6)	20 Feb 2021 00:31:10

US3162037

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:27:33

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject had onset of left hip pain in May2020, subsequently diagnosed as osteonecrosis. Admitted to hospital for planned surgery on 8FEB2021, had total left hip replacement that day, discharged to home on 9FEB2021'	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 17:47:49

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:27:33**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Feb 2021 17:47:49

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:27:33**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Feb 2021 17:47:49

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 15:27:33**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Feb 2021 17:47:49



US3162037

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:27:33

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Procedural related injuries and complications NEC, HLT: Non-site specific procedural complications, PT: Procedural pain, LLT: Postoperative pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Mar 2021 18:19:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Mar 2021 18:19:45
Data point term sent to Coder	System	20 Feb 2021 05:49:02
User entered 'PAIN from LEFT HIP REPLACEMENT' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	20 Feb 2021 05:48:15
Data point term sent to Coder	System	20 Feb 2021 05:48:02
User entered 'pain due to left hip replacement'	Judith Kirstein (b) (4) (b) (4)	20 Feb 2021 05:47:39

US3162037

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:27:33

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	20 Feb 2021 05:47:39

US3162037

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:27:33

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	20 Feb 2021 05:47:39

US3162037

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:27:33

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	20 Feb 2021 05:47:39

US3162037

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:27:33

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered '8 Feb 2021'	Judith Kirstein (b) (4) (b) (4)	20 Feb 2021 05:47:39

US3162037

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:27:33

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered empty.	Judith Kirstein (b) (4) (b) (4)	20 Feb 2021 05:47:39

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:27:33**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Feb 2021 05:47:39

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:27:33**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	20 Feb 2021 05:47:39



US3162037

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:27:33

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered empty.	Judith Kirstein (b) (4) (b) (4)	20 Feb 2021 05:47:39

US3162037

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:27:33

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered empty.	Judith Kirstein (b) (4) (b) (4)	20 Feb 2021 05:47:39

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:27:33**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Feb 2021 05:47:39

US3162037

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:27:33

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered 'Grade 3/Severe (Grade 3/Severe)'	Judith Kirstein (b) (4) (b) (4)	20 Feb 2021 05:47:39

US3162037

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:27:33

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	20 Feb 2021 05:47:39

US3162037

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:27:33

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered '0'	Judith Kirstein (b) (4) (b) (4)	20 Feb 2021 05:47:39

US3162037

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:27:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered '0'	Judith Kirstein (b) (4) (b) (4)	20 Feb 2021 05:47:39

US3162037

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:27:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered '0'	Judith Kirstein (b) (4) (b) (4)	20 Feb 2021 05:47:39



US3162037

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:27:33

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered empty.	Judith Kirstein (b) (4) (b) (4)	20 Feb 2021 05:47:39

US3162037

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:27:33

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered empty.	Judith Kirstein (b) (4) (b) (4)	20 Feb 2021 05:47:39

US3162037

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:27:33

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered empty.	Judith Kirstein (b) (4) (b) (4)	20 Feb 2021 05:47:39

US3162037

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:27:33

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered empty.	Judith Kirstein (b) (4) (b) (4)	20 Feb 2021 05:47:39

US3162037

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:27:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered '0'	Judith Kirstein (b) (4) (b) (4)	20 Feb 2021 05:47:39

US3162037

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:27:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered '0'	Judith Kirstein (b) (4) (b) (4)	20 Feb 2021 05:47:39

US3162037

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:27:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered '0'	Judith Kirstein (b) (4) (b) (4)	20 Feb 2021 05:47:39

US3162037

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:27:33

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered 'Not Related (NOT RELATED)'	Judith Kirstein (b) (4) (b) (4)	20 Feb 2021 05:47:39



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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:27:33

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered 'Not Related (NOT RELATED)'	Judith Kirstein (b) (4) (b) (4)	20 Feb 2021 05:47:39

US3162037

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:27:33

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered 'Not Applicable (NOT APPLICABLE)'	Judith Kirstein (b) (4) (b) (4)	20 Feb 2021 05:47:39

US3162037

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:27:33

None

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered '0'	Judith Kirstein (b) (4) (b) (4)	20 Feb 2021 05:47:39

US3162037

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:27:33

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered '1'	Judith Kirstein (b) (4) (b) (4)	20 Feb 2021 05:47:39

US3162037

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:27:33

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered '0'	Judith Kirstein (b) (4) (b) (4)	20 Feb 2021 05:47:39

US3162037

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:27:33

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Judith Kirstein (b) (4) (b) (4)	20 Feb 2021 05:47:39

US3162037

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:27:33

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered empty.	Judith Kirstein (b) (4) (b) (4)	20 Feb 2021 05:47:39

US3162037

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:27:33

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered empty.	Judith Kirstein (b) (4) (b) (4)	20 Feb 2021 05:47:39



**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:27:33**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	20 Feb 2021 05:47:39

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 15:27:33**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Feb 2021 05:47:39

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:27:33**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:41

US3162037

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:27:33

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Pain in hip - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Apr 2021 23:45:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Apr 2021 23:45:42
Data point term sent to Coder	System	05 Apr 2021 23:44:38
User entered 'Worsening of left hip pain'	(b) (4), (b) (6)	05 Apr 2021 23:44:19

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:27:33**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Apr 2021 23:44:19

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:27:33**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 23:44:19

US3162037

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:27:33

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 23:44:19

US3162037

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:27:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered '01 Sep 2020'	(b) (4), (b) (6)	05 Apr 2021 23:44:19



**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:27:33**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 23:44:19

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:27:33**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:41
User entered empty.	System	05 Apr 2021 23:44:19

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:27:33**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 23:44:19

US3162037

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:27:33

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User closed query 'End date is prior to Start date. Please correct.' (Site from System).	System	05 Apr 2021 23:44:32
User entered '08 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 23:44:32
User opened query 'End date is prior to Start date. Please correct.' (Site from System).	System	05 Apr 2021 23:44:19
User entered '08 Feb 2020'	(b) (4), (b) (6)	05 Apr 2021 23:44:19

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:27:33**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 23:44:19

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:27:33**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:41
User entered empty.	System	05 Apr 2021 23:44:19

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:27:33**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	05 Apr 2021 23:44:19

US3162037

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:27:33

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 23:44:19



**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:27:33**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 23:44:19

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:27:33**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 23:44:19

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:27:33**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 23:44:19

US3162037

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:27:33

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 23:44:19

US3162037

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:27:33

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 23:44:19

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:27:33**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 23:44:19

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:27:33**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 23:44:19

US3162037

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:27:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 23:44:19



**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:27:33**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 23:44:19

US3162037

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:27:33

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 23:44:19

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:27:33**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	05 Apr 2021 23:44:19

US3162037

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:27:33

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	05 Apr 2021 23:44:19

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:27:33**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	05 Apr 2021 23:44:19

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:27:33**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 23:44:19

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:27:33**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered 'I'	(b) (4), (b) (6)	05 Apr 2021 23:44:19

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:27:33**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 23:44:19



**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:27:33**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	05 Apr 2021 23:44:19

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:27:33**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 23:44:19

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:27:33**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:15:33
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 23:44:19

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:27:33**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:41
User entered '0'	System	05 Apr 2021 23:44:19

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:27:33**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:41
User entered '1'	System	05 Apr 2021 23:44:19

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 15:27:33**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:41

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:27:33**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:46

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:27:33

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:46
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Hips osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Apr 2021 03:43:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Apr 2021 03:43:42
Data point term sent to Coder	System	20 Apr 2021 03:43:08
User entered 'osteoarthritis of left hip'	Judith Kirstein (b) (4) (b) (4)	20 Apr 2021 03:42:08



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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:27:33

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:46
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	20 Apr 2021 03:42:08

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:27:33**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:46
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	20 Apr 2021 03:42:08

US3162037

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:27:33

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:46
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	20 Apr 2021 03:42:08

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:27:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:46
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered '8 Jan 2021'	Judith Kirstein (b) (4) (b) (4)	20 Apr 2021 03:42:08

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:27:33**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:46
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered empty.	Judith Kirstein (b) (4) (b) (4)	20 Apr 2021 03:42:08

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:27:33**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:46
User entered empty.	System	20 Apr 2021 03:42:08

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:27:33**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:46
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	20 Apr 2021 03:42:08

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:27:33

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:46
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered '8 Feb 2021'	Judith Kirstein (b) (4) (b) (4)	20 Apr 2021 03:42:08



**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:27:33**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:46
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered empty.	Judith Kirstein (b) (4) (b) (4)	20 Apr 2021 03:42:08

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:27:33**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:46
User entered empty.	System	20 Apr 2021 03:42:08

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:27:33**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:46
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered 'Grade 3/Severe (Grade 3/Severe)'	Judith Kirstein (b) (4) (b) (4)	20 Apr 2021 03:42:08

US3162037

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:27:33

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:46
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	20 Apr 2021 03:42:08

US3162037

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:27:33

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:46
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 22:50:13
	(b) (4)	
User entered '0'	Judith Kirstein (b) (4)	20 Apr 2021 03:42:08
	(b) (4)	

US3162037

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:27:33

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:46
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered '0'	Judith Kirstein (b) (4) (b) (4)	20 Apr 2021 03:42:08

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:27:33**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:46
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered '0'	Judith Kirstein (b) (4) (b) (4)	20 Apr 2021 03:42:08

US3162037

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:27:33

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:46
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered empty.	Judith Kirstein (b) (4) (b) (4)	20 Apr 2021 03:42:08



US3162037

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:27:33

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:46
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered empty.	Judith Kirstein (b) (4) (b) (4)	20 Apr 2021 03:42:08

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:27:33**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:46
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered empty.	Judith Kirstein (b) (4) (b) (4)	20 Apr 2021 03:42:08

US3162037

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:27:33

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:46
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered empty.	Judith Kirstein (b) (4) (b) (4)	20 Apr 2021 03:42:08

US3162037

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:27:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:46
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered '0'	Judith Kirstein (b) (4) (b) (4)	20 Apr 2021 03:42:08

US3162037

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:27:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:46
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered '0'	Judith Kirstein (b) (4) (b) (4)	20 Apr 2021 03:42:08

US3162037

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:27:33

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:46
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered '0'	Judith Kirstein (b) (4) (b) (4)	20 Apr 2021 03:42:08

US3162037

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:27:33

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:46
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered 'Not Related (NOT RELATED)'	Judith Kirstein (b) (4) (b) (4)	20 Apr 2021 03:42:08

US3162037

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:27:33

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:46
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered 'Not Related (NOT RELATED)'	Judith Kirstein (b) (4) (b) (4)	20 Apr 2021 03:42:08



**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:27:33**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:46
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered 'Not Applicable (NOT APPLICABLE)'	Judith Kirstein (b) (4) (b) (4)	20 Apr 2021 03:42:08

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:27:33**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:46
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 22:50:13
	(b) (4)	
User entered '0'	Judith Kirstein (b) (4)	20 Apr 2021 03:42:08
	(b) (4)	

US3162037

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:27:33

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:46
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered '0'	Judith Kirstein (b) (4) (b) (4)	20 Apr 2021 03:42:08

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:27:33**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:46
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered 'I'	Judith Kirstein (b) (4) (b) (4)	20 Apr 2021 03:42:08

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:27:33**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:46
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Judith Kirstein (b) (4) (b) (4)	20 Apr 2021 03:42:08

US3162037

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:27:33

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:46
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered empty.	Judith Kirstein (b) (4) (b) (4)	20 Apr 2021 03:42:08

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:27:33**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:46
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User entered empty.	Judith Kirstein (b) (4) (b) (4)	20 Apr 2021 03:42:08

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:27:33**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:46
User entered '0'	System	20 Apr 2021 03:42:08



**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:27:33**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:46
User entered 'I'	System	20 Apr 2021 03:42:08

**US3162037**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 15:27:33**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:46

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:27:33

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:03:18
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:09:12
User closed query 'Please add con-meds associated with SAE to EDC. ' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 23:09:00
Query 'Please add con-meds associated with SAE to EDC. ' answered with 'See meds 20-31' (Site from CRA).	Judith Kirstein (b) (4)	15 Apr 2021 22:29:40
User opened query 'Please add con-meds associated with SAE to EDC. ' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 19:06:59
User signature succeeded.	Judith Kirstein (b) (4)	13 Feb 2021 01:34:22
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	06 Aug 2020 21:09:05

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:27:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	13 Feb 2021 01:34:22
	(b) (4)	
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: DRUGS FOR TREATMENT OF BONE DISEASES, ATC: DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION, ATC: BISPHOSPHONATES, PRODUCT: ALENDRONATE SODIUM, PRODUCTSYNONYM: ALENDRONATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Aug 2020 21:12:06
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Aug 2020 21:12:06
	(b) (4)	
Data point term sent to Coder	System	06 Aug 2020 21:10:51
User entered 'alendronate'	Jared Bradshaw (b) (4)	06 Aug 2020 21:09:58
	(b) (4)	

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:27:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:09:58

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:27:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'osteopenia'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:09:58

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:27:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered '70'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:09:58

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:27:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'mg (mg)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:09:58



US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:27:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:09:58

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:27:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'every week (QS)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:09:58

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:27:33

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:09:58

US3162037

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:27:33**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'Oral (ORAL)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:09:58

US3162037

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:27:33**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:09:58

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:27:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	13 Feb 2021 01:34:22
	(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.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 11:08:34
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	06 Aug 2020 21:09:58
User entered 'un Mar 2018'	Jared Bradshaw (b) (4)	06 Aug 2020 21:09:58
	(b) (4)	

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:27:33

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:09:58

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:27:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:09:58



US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:27:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:09:58

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:27:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:09:58

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:27:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 21:09:58

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:27:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 21:09:58

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:27:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	06 Aug 2020 21:09:58

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:27:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: FLUOXETINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Aug 2020 21:12:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Aug 2020 21:12:06
Data point term sent to Coder	System	06 Aug 2020 21:10:51
User entered 'fluoxetine'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:10:23

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:27:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:10:23

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:27:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'depression'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:10:23



US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:27:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered '40'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:10:23

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:27:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'mg (mg)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:10:23

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:27:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:10:23

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:27:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'once daily (QD)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:10:23

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:27:33

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:10:23

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:27:33**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'Oral (ORAL)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:10:23

US3162037

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:27:33**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:10:23

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:27:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	13 Feb 2021 01:34:22
	(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.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 11:43:30
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	06 Aug 2020 21:10:23
User entered 'un Mar 2018'	Jared Bradshaw (b) (4)	06 Aug 2020 21:10:23
	(b) (4)	



US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:27:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:10:23

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:27:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:10:23

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:27:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:10:23

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:27:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:10:23

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:27:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 21:10:23

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:27:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 21:10:23

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:27:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Aug 2020 21:10:23

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:27:33

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	13 Feb 2021 01:34:22
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL TARTRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Aug 2020 21:13:07
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Aug 2020 21:13:07
	(b) (4)	
Data point term sent to Coder	System	06 Aug 2020 21:11:52
User entered 'metoprolol tartrate'	Jared Bradshaw (b) (4)	06 Aug 2020 21:10:57
	(b) (4)	



US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:27:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:10:57

US3162037

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:27:33**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'hypertension'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:10:57

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:27:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered '25'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:10:57

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:27:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'mg (mg)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:10:57

US3162037

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:27:33**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:10:57

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:27:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'twice daily (BID)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:10:57

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:27:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:10:57

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:27:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'Oral (ORAL)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:10:57



US3162037

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:27:33**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:10:57

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:27:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	13 Feb 2021 01:34:22
	(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.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 11:43:40
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	06 Aug 2020 21:10:57
User entered 'un Jun 2018'	Jared Bradshaw (b) (4)	06 Aug 2020 21:10:57
	(b) (4)	

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:27:33

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:10:57

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:27:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:10:57

US3162037

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:27:33**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:10:57

US3162037

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:27:33**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:10:57

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:27:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	06 Aug 2020 21:10:57

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:27:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 21:10:57



**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:27:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Aug 2020 21:10:57

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:27:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	13 Feb 2021 01:34:22
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: ANTIARRHYTHMICS, CLASS I AND III, ATC: ANTIARRHYTHMICS, CLASS III, PRODUCT: DRONEDARONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Aug 2020 09:58:13
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Aug 2020 09:58:13
	(b) (4)	
Data point term sent to Coder	System	06 Aug 2020 21:11:54
User entered 'dronedarone'	Jared Bradshaw (b) (4)	06 Aug 2020 21:11:28
	(b) (4)	

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:27:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:11:28

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:27:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'atrial fibrillation'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:11:28

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:27:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered '400'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:11:28

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:27:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'mg (mg)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:11:28

US3162037

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:27:33**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:11:28

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:27:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'twice daily (BID)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:11:28



US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:27:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:11:28

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:27:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'Oral (ORAL)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:11:28

US3162037

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:27:33**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:11:28

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:27:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	13 Feb 2021 01:34:22
	(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.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 11:43:48
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	06 Aug 2020 21:11:28
User entered 'un May 2019'	Jared Bradshaw (b) (4)	06 Aug 2020 21:11:28
	(b) (4)	

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:27:33

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:11:28

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:27:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:11:28

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:27:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:11:28

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:27:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:11:28



**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:27:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	06 Aug 2020 21:11:28

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:27:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 21:11:28

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:27:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Aug 2020 21:11:28

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:27:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	13 Feb 2021 01:34:22
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: HYDROCODONE/ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Aug 2020 21:14:09
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Aug 2020 21:14:09
	(b) (4)	
Data point term sent to Coder	System	06 Aug 2020 21:12:55
User entered 'hydrocodone/acetaminophen'	Jared Bradshaw (b) (4)	06 Aug 2020 21:12:14
	(b) (4)	

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:27:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:12:14

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:27:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'osteoarthritis lower back'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:12:14

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:27:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered '5/325'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:12:14

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:27:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'mg (mg)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:12:14



US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:27:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:12:14

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:27:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'as needed (PRN)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:12:14

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:27:33

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:12:14

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:27:33**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'Oral (ORAL)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:12:14

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:27:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:12:14

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:27:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
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.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 11:43:56
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	06 Aug 2020 21:12:14
User entered 'un Mar 2018'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:12:14

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:27:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:12:14

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:27:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:12:14



US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:27:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:12:14

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:27:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:12:14

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:27:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 21:12:14

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:27:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 21:12:14

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:27:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 21:12:14

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:27:33

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	13 Feb 2021 01:34:22
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTI-PARKINSON DRUGS, ATC: DOPAMINERGIC AGENTS, ATC: DOPAMINE AGONISTS, PRODUCT: PRAMIPEXOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Sep 2020 06:05:53
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Sep 2020 06:05:53
	(b) (4)	
Data point term sent to Coder	System	15 Sep 2020 17:38:02
Coding entries removed.	Judith Kirstein (b) (4)	15 Sep 2020 17:37:03
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTI-PARKINSON DRUGS, ATC: DOPAMINERGIC AGENTS, ATC: DOPAMINE AGONISTS, PRODUCT: PRAMIPEXOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Aug 2020 21:14:08
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Aug 2020 21:14:08
	(b) (4)	
Data point term sent to Coder	System	06 Aug 2020 21:12:57
User entered 'pramipexole'	Jared Bradshaw (b) (4)	06 Aug 2020 21:12:50
	(b) (4)	

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:27:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:12:50

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:27:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'RESTLESS LEG SYNDROME, BILATERAL' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	15 Sep 2020 17:37:03
User entered 'restless leg syndrome'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:12:50



US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:27:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered '.25'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:12:50

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:27:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'mg (mg)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:12:50

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:27:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:12:50

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:27:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'once daily (QD)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:12:50

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:27:33

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:12:50

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:27:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'Oral (ORAL)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:12:50

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:27:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:12:50

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:27:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	13 Feb 2021 01:34:22
	(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.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 11:44:04
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	06 Aug 2020 21:12:50
User entered 'un May 2018'	Jared Bradshaw (b) (4)	06 Aug 2020 21:12:50
	(b) (4)	



US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:27:33

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:12:50

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:27:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:12:50

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:27:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:12:50

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:27:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:12:50

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:27:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 21:12:50

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:27:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 21:12:50

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:27:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Aug 2020 21:12:50

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:27:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	13 Feb 2021 01:34:22
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: PRAVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Aug 2020 21:15:34
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Aug 2020 21:15:34
	(b) (4)	
Data point term sent to Coder	System	06 Aug 2020 21:13:58
User entered 'pravastatin'	Jared Bradshaw (b) (4)	06 Aug 2020 21:13:17
	(b) (4)	



US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:27:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:13:17

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:27:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'hyperlipidemia'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:13:17

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:27:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered '80'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:13:17

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:27:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'mg (mg)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:13:17

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:27:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:13:17

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:27:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'once daily (QD)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:13:17

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:27:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:13:17

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:27:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'Oral (ORAL)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:13:17



US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:27:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:13:17

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:27:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	13 Feb 2021 01:34:22
	(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.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 11:44:12
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	06 Aug 2020 21:13:17
User entered 'un Mar 2018'	Jared Bradshaw (b) (4)	06 Aug 2020 21:13:17
	(b) (4)	

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:27:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:13:17

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:27:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:13:17

US3162037

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:27:33**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:13:17

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:27:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:13:17

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:27:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 21:13:17

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:27:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 21:13:17



**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:27:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Aug 2020 21:13:17

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:27:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	13 Feb 2021 01:34:22
	(b) (4)	
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: RIVAROXABAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 02:16:13
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 02:16:13
	(b) (4)	
Data point term sent to Coder	System	06 Aug 2020 21:13:58
User entered 'rivaroxaban'	Jared Bradshaw (b) (4)	06 Aug 2020 21:13:47
	(b) (4)	

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:27:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:13:47

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:27:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'atrial fibrillation'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:13:47

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:27:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered '20'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:13:47

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:27:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'mg (mg)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:13:47

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:27:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:13:47

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:27:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'once daily (QD)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:13:47



US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:27:33

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:13:47

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:27:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'Oral (ORAL)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:13:47

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:27:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:13:47

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:27:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	13 Feb 2021 01:34:22
	(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.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 11:44:21
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	06 Aug 2020 21:13:47
User entered 'un Mar 2018'	Jared Bradshaw (b) (4)	06 Aug 2020 21:13:47
	(b) (4)	

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:27:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:13:47

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:27:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:13:47

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:27:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:13:47

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:27:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:13:47



**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:27:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 21:13:47

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:27:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 21:13:47

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:27:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Aug 2020 21:13:47

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:27:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	13 Feb 2021 01:34:22
	(b) (4)	
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Sep 2020 07:19:53
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Sep 2020 07:19:53
	(b) (4)	
Data point term sent to Coder	System	24 Sep 2020 04:30:45
Coding entries removed.	Judith Kirstein (b) (4)	24 Sep 2020 04:30:15
	(b) (4)	
User entered 'IBUPROFEN' reason for change: Data Entry Error	Judith Kirstein (b) (4)	24 Sep 2020 04:30:15
	(b) (4)	
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Sep 2020 10:03:38
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Sep 2020 10:03:38
	(b) (4)	
Data point term sent to Coder	System	01 Sep 2020 20:14:40
Coding entries removed.	Cynthia Kunakom (b) (4)	01 Sep 2020 20:13:59
	(b) (4)	

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:27:33

[Name of Medication](#)

Audit	User	Time (GMT)
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.	Coder Import (b) (4) (b) (4)	06 Aug 2020 21:16:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Aug 2020 21:16:05
Data point term sent to Coder	System	06 Aug 2020 21:14:59
User entered 'ibuprophen'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:14:17

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:27:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:14:17

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:27:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'OSTEOARTHRITIS LOWER BACK (left and right hip pain)' reason for change: Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 20:13:59
User entered 'osteoarthritis lower back'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:14:17

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:27:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered '800'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:14:17



US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:27:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'mg (mg)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:14:17

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:27:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:14:17

US3162037

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:27:33**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'as needed (PRN)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:14:17

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:27:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:14:17

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:27:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'Oral (ORAL)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:14:17

US3162037

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:27:33**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:14:17

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:27:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
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.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 11:44:29
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	06 Aug 2020 21:14:17
User entered '18 Dec 2019'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:14:17

US3162037

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:27:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:14:17



US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:27:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:14:17

US3162037

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:27:33**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:14:17

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:27:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 21:14:17

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:27:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 21:14:17

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:27:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 21:14:17

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:27:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 21:14:17

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:27:33

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Aug 2020 02:12:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Aug 2020 02:12:24
Data point term sent to Coder	System	22 Aug 2020 02:11:43
User entered 'Naproxen'	Jared Bradshaw (b) (4) (b) (4)	22 Aug 2020 02:11:40

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:27:33

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	22 Aug 2020 02:11:40



**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:27:33**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'headache'	Jared Bradshaw (b) (4) (b) (4)	22 Aug 2020 02:11:40

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:27:33**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered '660'	Jared Bradshaw (b) (4) (b) (4)	22 Aug 2020 02:11:40

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:27:33**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'mg (mg)'	Jared Bradshaw (b) (4) (b) (4)	22 Aug 2020 02:11:40

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:27:33

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	22 Aug 2020 02:11:40

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:27:33

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'once (ONCE)'	Jared Bradshaw (b) (4) (b) (4)	22 Aug 2020 02:11:40

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:27:33

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	22 Aug 2020 02:11:40

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:27:33**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'Oral (ORAL)'	Jared Bradshaw (b) (4) (b) (4)	22 Aug 2020 02:11:40

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:27:33

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	22 Aug 2020 02:11:40



**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:27:33**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered '07 Aug 2020'	Jared Bradshaw (b) (4) (b) (4)	22 Aug 2020 02:11:40

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:27:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	22 Aug 2020 02:11:40

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:27:33**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	22 Aug 2020 02:11:40

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:27:33**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered '07 Aug 2020'	Jared Bradshaw (b) (4) (b) (4)	22 Aug 2020 02:11:40

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:27:33**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	22 Aug 2020 02:11:40

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:27:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:09
User entered empty.	System	22 Aug 2020 02:11:40

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:27:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:09
User entered empty.	System	22 Aug 2020 02:11:40

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:27:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:09
User entered empty.	System	22 Aug 2020 02:11:40



US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:27:33

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:13
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, consider recording an AE of Worsening LEFT AND RIGHT HIP PAIN during this timeframe; update Con Med indication or provide clarification. ' (Site from DM). Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, consider recording an AE of Worsening LEFT AND RIGHT HIP PAIN during this timeframe; update Con Med indication or provide clarification. ' answered with 'did not worsen, per PI' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 13:09:39
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, consider recording an AE of Worsening LEFT AND RIGHT HIP PAIN during this timeframe; update Con Med indication or provide clarification. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	17 Mar 2021 20:59:12
	(b) (4), (b) (6)	16 Mar 2021 12:12:12
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: COXIBS, PRODUCT: CELECOXIB - version WHODrug-Global-B3\\202003.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 02:18:34
Data point term sent to Coder	System	31 Aug 2020 15:18:59
User entered 'Celecoxib'	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:18:15

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:27:33

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:13
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:18:15

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:27:33

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:13
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User closed query 'Per DM CLR: Please review indication. RIGHT HIP PAIN is not listed on either Medical History (ongoing) or Adverse Event page. Reconcile and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 14:37:29
Query 'Per DM CLR: Please review indication. RIGHT HIP PAIN is not listed on either Medical History (ongoing) or Adverse Event page. Reconcile and update as appropriate. ' answered with 'Added right hip pain to MH' (Site from DM).	Judith Kirstein (b) (4) (b) (4)	15 Sep 2020 06:06:45
User opened query 'Per DM CLR: Please review indication. RIGHT HIP PAIN is not listed on either Medical History (ongoing) or Adverse Event page. Reconcile and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 10:51:53
User entered 'left and right hip pain'	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:18:15

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:27:33

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:13
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered '100'	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:18:15

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:27:33

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:13
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'mg (mg)'	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:18:15

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:27:33

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:13
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:18:15

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:27:33**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:13
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'twice daily (BID)'	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:18:15

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:27:33

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:13
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:18:15



**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:27:33**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:13
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'Oral (ORAL)'	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:18:15

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:27:33

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:13
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:18:15

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:27:33**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:13
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered '17 Aug 2020'	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:18:15

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:27:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:13
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:18:15

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:27:33

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:13
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:44
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	28 Feb 2021 19:06:47
User entered 'No (N)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	28 Feb 2021 19:06:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:18:15

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:27:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:13
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:44
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	28 Feb 2021 19:06:47
User entered '7 Feb 2021' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	28 Feb 2021 19:06:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:18:15

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:27:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:13
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:18:15

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:27:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:13
User entered '2'	System	31 Aug 2020 15:18:15



**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:27:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:13
User entered '1'	System	31 Aug 2020 15:18:15

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:27:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:13
User entered '804 (804)'	System	31 Aug 2020 15:18:15

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:27:33

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:17
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening OSTEOARTHRITIS (LOWER BACK) should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 13:38:22
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening OSTEOARTHRITIS (LOWER BACK) should be recorded, and update con med indication or provide clarification. ' answered with 'Her condition did not worsen. It had been hurting badly since May.' (Site from DM).	Judith Kirstein (b) (4) (b) (4)	06 Oct 2020 01:18:43
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening OSTEOARTHRITIS (LOWER BACK) should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	04 Oct 2020 11:08:01
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening OSTEOARTHRITIS should be recorded, and update con med indication or provide clarification. ' canceled (Site from DM).		04 Oct 2020 11:07:44
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening OSTEOARTHRITIS should be recorded, and update con med indication or provide clarification. ' (Site from DM).		04 Oct 2020 11:07:38

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:27:33

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: TRIAMCINOLONE ACETONIDE, PRODUCTSYNONYM: KENALOG [TRIAMCINOLONE ACETONIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Sep 2020 15:42:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Sep 2020 15:42:00
Data point term sent to Coder	System	21 Sep 2020 14:30:12
User entered 'kenalog'	Cynthia Kunakom (b) (4)	21 Sep 2020 14:30:05

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:27:33**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:17
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	21 Sep 2020 14:30:05

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:27:33**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:17
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'osteoarthritis (lower back)'	Cynthia Kunakom (b) (4) (b) (4)	21 Sep 2020 14:30:05

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:27:33**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:17
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered '40'	Cynthia Kunakom (b) (4) (b) (4)	21 Sep 2020 14:30:05

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:27:33

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:17
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'mg (mg)'	Cynthia Kunakom (b) (4) (b) (4)	21 Sep 2020 14:30:05



US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:27:33

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:17
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	21 Sep 2020 14:30:05

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:27:33**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:17
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'once (ONCE)'	Cynthia Kunakom (b) (4) (b) (4)	21 Sep 2020 14:30:05

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:27:33

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:17
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	21 Sep 2020 14:30:05

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:27:33**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:17
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'Other (OTHER)'	Cynthia Kunakom (b) (4) (b) (4)	21 Sep 2020 14:30:05

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:27:33

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:17
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'Intraarticular'	Cynthia Kunakom (b) (4) (b) (4)	21 Sep 2020 14:30:05

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:27:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:17
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered '16 Sep 2020'	Cynthia Kunakom (b) (4) (b) (4)	21 Sep 2020 14:30:05

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:27:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:17
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	21 Sep 2020 14:30:05

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:27:33**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:17
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	21 Sep 2020 14:30:05



US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:27:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:17
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered '16 Sep 2020'	Cynthia Kunakom (b) (4) (b) (4)	21 Sep 2020 14:30:05

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:27:33**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:17
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	21 Sep 2020 14:30:05

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:27:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:17
User entered empty.	System	21 Sep 2020 14:30:05

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:27:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:17
User entered empty.	System	21 Sep 2020 14:30:05

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:27:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:17
User entered empty.	System	21 Sep 2020 14:30:05

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:27:33

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:23
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 01:23:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 01:23:44
Data point term sent to Coder	System	24 Sep 2020 01:23:30
User entered 'NAPROXEN'	Judith Kirstein (b) (4) (b) (4)	24 Sep 2020 01:23:14

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:27:33

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:23
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	24 Sep 2020 01:23:14

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:27:33**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:23
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'LEFT SHOULDER PAIN'	Judith Kirstein (b) (4) (b) (4)	24 Sep 2020 01:23:14



**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:27:33**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:23
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered '660'	Judith Kirstein (b) (4) (b) (4)	24 Sep 2020 01:23:14

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:27:33

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:23
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'mg (mg)'	Judith Kirstein (b) (4) (b) (4)	24 Sep 2020 01:23:14

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:27:33

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:23
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered empty.	Judith Kirstein (b) (4) (b) (4)	24 Sep 2020 01:23:14

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:27:33**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:23
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'as needed (PRN)'	Judith Kirstein (b) (4) (b) (4)	24 Sep 2020 01:23:14

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:27:33

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:23
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered empty.	Judith Kirstein (b) (4) (b) (4)	24 Sep 2020 01:23:14

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:27:33**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:23
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'Oral (ORAL)'	Judith Kirstein (b) (4) (b) (4)	24 Sep 2020 01:23:14

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:27:33

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:23
User signature succeeded.	Judith Kirstein (b) (4)	13 Feb 2021 01:34:22
	(b) (4)	
User entered empty.	Judith Kirstein (b) (4)	24 Sep 2020 01:23:14
	(b) (4)	

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:27:33**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:23
User signature succeeded.	Judith Kirstein (b) (4)	13 Feb 2021 01:34:22
	(b) (4)	
User entered '23 Aug 2020'	Judith Kirstein (b) (4)	24 Sep 2020 01:23:14
	(b) (4)	



**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:27:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:23
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered '0'	Judith Kirstein (b) (4) (b) (4)	24 Sep 2020 01:23:14

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:27:33

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:23
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'No (N)' reason for change: New Information	Jessica Fisher (b) (4)	26 Nov 2020 01:02:44
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	24 Sep 2020 01:23:14

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:27:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:23
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered '13 Nov 2020' reason for change: New Information	Jessica Fisher (b) (4)	26 Nov 2020 01:02:44
User entered empty.	Judith Kirstein (b) (4) (b) (4)	24 Sep 2020 01:23:14

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:27:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:23
User signature succeeded.	Judith Kirstein (b) (4)	13 Feb 2021 01:34:22
	(b) (4)	
User entered 'No (N)'	Judith Kirstein (b) (4)	24 Sep 2020 01:23:14
	(b) (4)	

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:27:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:23
User entered empty.	System	24 Sep 2020 01:23:14

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:27:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:23
User entered empty.	System	24 Sep 2020 01:23:14

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:27:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:23
User entered empty.	System	24 Sep 2020 01:23:14

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:27:33

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: TRIAMCINOLONE ACETONIDE, PRODUCTSYNONYM: KENALOG [TRIAMCINOLONE ACETONIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 10:29:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 10:29:55
Data point term sent to Coder	System	28 Sep 2020 16:29:58
User entered 'Kenalog'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:29:06



US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:27:33

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:29:06

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:27:33

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'right hip pain'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:29:06

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:27:33

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered '40'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:29:06

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:27:33

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'mg (mg)'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:29:06

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:27:33

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:29:06

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:27:33

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'once (ONCE)'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:29:06

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:27:33

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:29:06

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:27:33

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'Other (OTHER)'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:29:06



US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:27:33

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'intraarticular'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:29:06

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:27:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered '16 Sep 2020'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:29:06

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 15:27:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:29:06

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:27:33

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Sep 2020 16:29:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Sep 2020 16:29:13
User entered 'No (N)' reason for change: Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:29:13
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Sep 2020 16:29:06
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:29:06

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:27:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered '16 Sep 2020'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:29:06

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:27:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:29:06

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 15:27:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:33
User entered empty.	System	28 Sep 2020 16:29:06

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:27:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:33
User entered empty.	System	28 Sep 2020 16:29:06



US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:27:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:33
User entered empty.	System	28 Sep 2020 16:29:06

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:27:33

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:38
User closed query 'Please update eSource and EDC when medical records are received for the SAE of Osteonecrosis Hip Pain. Thank you.' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 00:56:02
Query 'Please update eSource and EDC when medical records are received for the SAE of Osteonecrosis Hip Pain. Thank you.' answered with 'Updated. When the Kenalog was given in Sep, it was not yet known that she had developing AVN' (Site from CRA).	Judith Kirstein (b) (4) (b) (4)	13 Apr 2021 22:57:02
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: TRIAMCINOLONE ACETONIDE, PRODUCTSYNONYM: KENALOG [TRIAMCINOLONE ACETONIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 15:30:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 15:30:33
Data point term sent to Coder	System	05 Apr 2021 23:38:37
Coding entries removed.	(b) (4), (b) (6)	05 Apr 2021 23:38:17
User opened query 'Please update eSource and EDC when medical records are received for the SAE of Osteonecrosis Hip Pain. Thank you.' (Site from CRA).	(b) (4), (b) (6)	20 Feb 2021 00:32:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:27:33

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: TRIAMCINOLONE ACETONIDE, PRODUCTSYNONYM: KENALOG [TRIAMCINOLONE ACETONIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 08:23:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 08:23:58
Data point term sent to Coder	System	28 Sep 2020 16:29:59
User entered 'Kenalog'	Cynthia Kunakom (b) (4)	28 Sep 2020 16:29:52

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 15:27:33**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:29:52

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:27:33

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:44
Signature has been broken.	(b) (4), (b) (6)	05 Apr 2021 23:38:17
User entered 'Worsening of left hip pain' reason for change: New Information	(b) (4), (b) (6)	05 Apr 2021 23:38:17
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User closed query 'Per DM CLR: This medication was added after IP admin. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring an added medication. If yes, please add the applicable AE entry or explain the reason for change in regimen.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 18:41:06
Query 'Per DM CLR: This medication was added after IP admin. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring an added medication. If yes, please add the applicable AE entry or explain the reason for change in regimen.' answered with 'No worsening. The pain was bad all through the summer and she finally got into an ortho who chose to try kenalog injection' (Site from DM).	Judith Kirstein (b) (4) (b) (4)	28 Nov 2020 00:22:27
User opened query 'Per DM CLR: This medication was added after IP admin. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring an added medication. If yes, please add the applicable AE entry or explain the reason for change in regimen.' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 13:39:32
User entered 'left hip pain'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:29:52

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:27:33

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered '40'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:29:52

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:27:33

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'mg (mg)'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:29:52

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:27:33

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:29:52



US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:27:33

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'once (ONCE)' reason for change: Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	05 Oct 2020 16:25:57
User entered 'other (OTHER)'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:29:52

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:27:33

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User closed query 'Per DM CLR: Please review the Frequency as this medication is not a known frequency. Please update the Frequency as appropriate (e.g. Once, OD, etc.).' (Site from DM). Query 'Per DM CLR: Please review the Frequency as this medication is not a known frequency. Please update the Frequency as appropriate (e.g. Once, OD, etc.).' answered with 'Updated.' (Site from DM).	(b) (4), (b) (6) Cynthia Kunakom (b) (4) (b) (4)	11 Oct 2020 12:31:49 05 Oct 2020 16:26:04
User entered empty; reason for change Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	05 Oct 2020 16:25:57
User opened query 'Per DM CLR: Please review the Frequency as this medication is not a known frequency. Please update the Frequency as appropriate (e.g. Once, OD, etc.).' (Site from DM). User entered 'intraarticular'	(b) (4), (b) (6) Cynthia Kunakom (b) (4) (b) (4)	04 Oct 2020 11:08:33 28 Sep 2020 16:29:52

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:27:33

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'Other (OTHER)'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:29:52

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:27:33

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'intraarticular'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:29:52

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 15:27:33**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered '22 Sep 2020'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:29:52

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 15:27:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:29:52

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 15:27:33**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:29:52

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:27:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User entered '22 Sep 2020'	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:29:52



US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:27:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	13 Feb 2021 01:34:22
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Sep 2020 16:29:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Sep 2020 16:29:56
User entered 'No (N)' reason for change: Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:29:56
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Sep 2020 16:29:52
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	28 Sep 2020 16:29:52

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 15:27:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:38
User entered empty.	System	28 Sep 2020 16:29:52

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 15:27:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:38
User entered empty.	System	28 Sep 2020 16:29:52

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 15:27:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:38
User entered empty.	System	28 Sep 2020 16:29:52

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:27:33

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:44
User closed query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med CELECOXIB #11 (Start date 17 AUG 2020- ongoing). 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 Mar 2021 18:15:26
Query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med CELECOXIB #11 (Start date 17 AUG 2020- ongoing). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate. ' answered with 'New indication: Pain from left hip replacement' (Site from DM).	Judith Kirstein (b) (4) (b) (4)	28 Feb 2021 19:05:27
User opened query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med CELECOXIB #11 (Start date 17 AUG 2020- ongoing). 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)	27 Feb 2021 10:26:49
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: COXIBS, PRODUCT: CELECOXIB - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 13:20:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 13:20:15
Data point term sent to Coder	System	23 Feb 2021 04:11:54
User entered 'celecoxib'	Jessica Fisher (b) (4) (b) (4)	23 Feb 2021 04:11:15

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:27:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:44
User entered 'No (N)'	Jessica Fisher (b) (4) (b) (4)	23 Feb 2021 04:11:15

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:27:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:44
User entered 'pain from left hip replacement'	Jessica Fisher (b) (4) (b) (4)	23 Feb 2021 04:11:15

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:27:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:44
User entered '200'	Jessica Fisher (b) (4) (b) (4)	23 Feb 2021 04:11:15



US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:27:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:44
User entered 'mg (mg)'	Jessica Fisher (b) (4)	23 Feb 2021 04:11:15

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:27:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:44
User entered empty.	Jessica Fisher (b) (4) (b) (4)	23 Feb 2021 04:11:15

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:27:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:44
User entered 'twice daily (BID)'	Jessica Fisher (b) (4) (b) (4)	23 Feb 2021 04:11:15

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:27:33

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:44
User entered empty.	Jessica Fisher (b) (4) (b) (4)	23 Feb 2021 04:11:15

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:27:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:44
User entered 'Oral (ORAL)'	Jessica Fisher (b) (4) (b) (4)	23 Feb 2021 04:11:15

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:27:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:44
User entered empty.	Jessica Fisher (b) (4) (b) (4)	23 Feb 2021 04:11:15

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:27:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:44
User entered '08 Feb 2021'	Jessica Fisher (b) (4) (b) (4)	23 Feb 2021 04:11:15

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:27:33

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:44
User entered '0'	Jessica Fisher (b) (4)	23 Feb 2021 04:11:15



US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:27:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:44
User entered 'Yes (Y)'	Jessica Fisher (b) (4) (b) (4)	23 Feb 2021 04:11:15

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:27:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:44
User entered empty.	Jessica Fisher (b) (4) (b) (4)	23 Feb 2021 04:11:15

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:27:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:44
User entered 'No (N)'	Jessica Fisher (b) (4) (b) (4)	23 Feb 2021 04:11:15

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 15:27:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	23 Feb 2021 04:11:15

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 15:27:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Feb 2021 04:11:15

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 15:27:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Feb 2021 04:11:15

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:27:33

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:44
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE;PARACETAMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 12:54:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 12:54:37
Data point term sent to Coder	System	23 Feb 2021 04:12:54
User entered 'oxycodone/acetaminophen'	Jessica Fisher (b) (4) (b) (4)	23 Feb 2021 04:12:34

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 15:27:33**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:44
User entered 'No (N)'	Jessica Fisher (b) (4)	23 Feb 2021 04:12:34



**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 15:27:33**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:44
User entered 'pain from left hip replacement'	Jessica Fisher (b) (4)	23 Feb 2021 04:12:34

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 15:27:33**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:44
User entered '5/325'	Jessica Fisher (b) (4)	23 Feb 2021 04:12:34

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:27:33

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:44
User entered 'mg (mg)'	Jessica Fisher (b) (4)	23 Feb 2021 04:12:34

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:27:33

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:44
User entered empty.	Jessica Fisher (b) (4)	23 Feb 2021 04:12:34

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 15:27:33**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:44
User entered 'as needed (PRN)'	Jessica Fisher (b) (4)	23 Feb 2021 04:12:34

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:27:33

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:44
User entered empty.	Jessica Fisher (b) (4)	23 Feb 2021 04:12:34

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 15:27:33**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:44
User entered 'Oral (ORAL)'	Jessica Fisher (b) (4)	23 Feb 2021 04:12:34

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 15:27:33**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:44
User entered empty.	Jessica Fisher (b) (4)	23 Feb 2021 04:12:34



**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 15:27:33**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:44
User entered '08 Feb 2021'	Jessica Fisher (b) (4)	23 Feb 2021 04:12:34

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 15:27:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:44
User entered '0'	Jessica Fisher (b) (4)	23 Feb 2021 04:12:34

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:27:33

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:44
User entered 'No (N)' reason for change: New Information	Jessica Fisher (b) (4)	27 Mar 2021 03:29:56
User entered 'Yes (Y)'	Jessica Fisher (b) (4)	23 Feb 2021 04:12:34

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:27:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:44
User entered '19 Mar 2021' reason for change: New Information	Jessica Fisher (b) (4)	27 Mar 2021 03:29:56
User entered empty.	Jessica Fisher (b) (4)	23 Feb 2021 04:12:34

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 15:27:33**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:58
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:44
User entered 'No (N)'	Jessica Fisher (b) (4)	23 Feb 2021 04:12:34

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 15:27:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:58
User entered empty.	System	23 Feb 2021 04:12:34

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 15:27:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:58
User entered empty.	System	23 Feb 2021 04:12:34

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 15:27:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:47:58
User entered empty.	System	23 Feb 2021 04:12:34



US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:27:33

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:44
User closed query 'Per DM CLR: this Con Med was added/ had dose increased on 20 NOV 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 10:21:42
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: HYDROCODONE/ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 23:40:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 23:40:40
Data point term sent to Coder Coding entries removed.	System Judith Kirstein (b) (4) (b) (4)	05 Apr 2021 23:39:37 05 Apr 2021 23:39:01
Query 'Per DM CLR: this Con Med was added/ had dose increased on 20 NOV 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' answered with 'AE has been added' (Site from DM).	Judith Kirstein (b) (4) (b) (4)	05 Apr 2021 23:38:30
User opened query 'Per DM CLR: this Con Med was added/ had dose increased on 20 NOV 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 04:16:55

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:27:33

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: HYDROCODONE/ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 20:57:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 20:57:19
Data point term sent to Coder	System	29 Mar 2021 20:55:52
User entered 'Hydrocodone/Acetaminophen'	(b) (4), (b) (6) (b) (4)	29 Mar 2021 20:55:00

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:27:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:44
User entered 'No (N)'	(b) (4), (b) (6)	29 Mar 2021 20:55:00

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:27:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:44
User entered 'RIGHT HIP PAIN and worsening of left hip pain' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	05 Apr 2021 23:39:01
User entered 'Left and right hip pain'	(b) (4), (b) (6)	29 Mar 2021 20:55:00

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:27:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:44
User entered '5/325'	(b) (4), (b) (6)	29 Mar 2021 20:55:00

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:27:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:44
User entered 'mg (mg)'	(b) (4), (b) (6)	29 Mar 2021 20:55:00

US3162037

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:27:33**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:44
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 20:55:00

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:27:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:44
User entered 'as needed (PRN)'	(b) (4), (b) (6)	29 Mar 2021 20:55:00



US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:27:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:44
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 20:55:00

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:27:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:44
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	29 Mar 2021 20:55:00

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:27:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:44
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 20:55:00

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:27:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:44
User entered '20 Nov 2020'	(b) (4), (b) (6)	29 Mar 2021 20:55:00

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:27:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:44
User entered '0'	(b) (4), (b) (6)	29 Mar 2021 20:55:00

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:27:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Mar 2021 20:55:00

US3162037

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:27:33**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:44
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 20:55:00

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:27:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:44
User entered 'No (N)'	(b) (4), (b) (6)	29 Mar 2021 20:55:00



**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:27:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 20:55:00

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:27:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 20:55:00

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:27:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 20:55:00

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:27:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:44
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: CODEINE PHOSPHATE;PARACETAMOL, PRODUCTSYNONYM: TYLENOL WITH CODEINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 20:58:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 20:58:15
Data point term sent to Coder	System	29 Mar 2021 20:56:53
User entered 'Tylenol with codeine'	(b) (4), (b) (6) (b) (4)	29 Mar 2021 20:56:05

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:27:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:44
User entered 'No (N)'	(b) (4), (b) (6)	29 Mar 2021 20:56:05

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:27:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:44
User entered 'Left and right hip pain'	(b) (4), (b) (6) (b) (4)	29 Mar 2021 20:56:05

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:27:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:44
User entered '30/300'	(b) (4), (b) (6)	29 Mar 2021 20:56:05

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:27:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:44
User entered 'mg (mg)'	(b) (4), (b) (6)	29 Mar 2021 20:56:05



US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:27:33

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:44
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 20:56:05

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:27:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:44
User entered 'as needed (PRN)'	(b) (4), (b) (6)	29 Mar 2021 20:56:05

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:27:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:44
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 20:56:05

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:27:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:44
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	29 Mar 2021 20:56:05

US3162037

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 15:27:33**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:44
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 20:56:05

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:27:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:44
User entered '13 Nov 2020'	(b) (4), (b) (6)	29 Mar 2021 20:56:05

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:27:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:44
User entered '0'	(b) (4), (b) (6)	29 Mar 2021 20:56:05

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:27:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Mar 2021 20:56:05



US3162037

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 15:27:33**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:44
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 20:56:05

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:27:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	14 Apr 2021 18:17:44
User entered 'No (N)'	(b) (4), (b) (6)	29 Mar 2021 20:56:05

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 15:27:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 20:56:05

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 15:27:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 20:56:05

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 15:27:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 20:56:05

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:27:33

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:17
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:27
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: MIDAZOLAM HYDROCHLORIDE, PRODUCTSYNONYM: VERSED - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 12:46:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 12:46:45
Data point term sent to Coder	System	15 Apr 2021 21:44:47
User entered 'Versed'	(b) (4), (b) (6)	15 Apr 2021 21:44:38

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:27:33

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:17
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:27
User entered 'No (N)'	(b) (4), (b) (6)	15 Apr 2021 21:44:38

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 15:27:33**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:17
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:27
User entered 'Sedation for left total hip arthroplasty'	(b) (4), (b) (6)	15 Apr 2021 21:44:38



**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 15:27:33**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:17
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:27
User entered '2'	(b) (4), (b) (6)	15 Apr 2021 21:44:38

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 15:27:33**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:17
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:27
User entered 'mg (mg)'	(b) (4), (b) (6)	15 Apr 2021 21:44:38

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:27:33

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:17
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:27
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 21:44:38

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 15:27:33**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:17
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:27
User entered 'once (ONCE)'	(b) (4), (b) (6)	15 Apr 2021 21:44:38

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:27:33

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:17
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:27
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 21:44:38

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 15:27:33**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:17
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:27
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	15 Apr 2021 21:44:38

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 15:27:33**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:17
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:27
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 21:44:38

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 15:27:33**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:17
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:27
User entered '08 Feb 2021'	(b) (4), (b) (6)	15 Apr 2021 21:44:38



**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 15:27:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:17
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:27
User entered '0'	(b) (4), (b) (6)	15 Apr 2021 21:44:38

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 15:27:33**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:17
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:27
User entered 'No (N)'	(b) (4), (b) (6)	15 Apr 2021 21:44:38

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:27:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:17
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:27
User entered '08 Feb 2021'	(b) (4), (b) (6)	15 Apr 2021 21:44:38

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:27:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:17
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:27
User entered 'No (N)'	(b) (4), (b) (6)	15 Apr 2021 21:44:38

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 15:27:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:17
User entered empty.	System	15 Apr 2021 21:44:38

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 15:27:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:17
User entered empty.	System	15 Apr 2021 21:44:38

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 15:27:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:17
User entered empty.	System	15 Apr 2021 21:44:38

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:27:33

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:21
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:26
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: LINCOSAMIDES, PRODUCT: CLINDAMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 09:38:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 09:38:55
Data point term sent to Coder	System	15 Apr 2021 21:45:48
User entered 'Clindamycin'	(b) (4), (b) (6)	15 Apr 2021 21:45:41



US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:27:33

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:21
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Apr 2021 21:45:41

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 15:27:33**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:21
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:26
User entered 'Prevent infection from left total hip arthroplasty'	(b) (4), (b) (6)	15 Apr 2021 21:45:41

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 15:27:33**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:21
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:26
User entered '900'	(b) (4), (b) (6)	15 Apr 2021 21:45:41

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:27:33

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:21
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:26
User entered 'mg (mg)'	(b) (4), (b) (6)	15 Apr 2021 21:45:41

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 15:27:33**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:21
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:26
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 21:45:41

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 15:27:33**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:21
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:26
User entered 'once (ONCE)'	(b) (4), (b) (6)	15 Apr 2021 21:45:41

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:27:33

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:21
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:26
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 21:45:41

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 15:27:33**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:21
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:26
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	15 Apr 2021 21:45:41



US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:27:33

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:21
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:26
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 21:45:41

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 15:27:33**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:21
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:26
User entered '08 Feb 2021'	(b) (4), (b) (6)	15 Apr 2021 21:45:41

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:27:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:21
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:26
User entered '0'	(b) (4), (b) (6)	15 Apr 2021 21:45:41

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 15:27:33**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:21
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:26
User entered 'No (N)'	(b) (4), (b) (6)	15 Apr 2021 21:45:41

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 15:27:33**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:21
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:26
User entered '08 Feb 2021'	(b) (4), (b) (6)	15 Apr 2021 21:45:41

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 15:27:33**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:21
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:26
User entered 'No (N)'	(b) (4), (b) (6)	15 Apr 2021 21:45:41

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 15:27:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:21
User entered empty.	System	15 Apr 2021 21:45:41

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 15:27:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:21
User entered empty.	System	15 Apr 2021 21:45:41



**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 15:27:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:21
User entered empty.	System	15 Apr 2021 21:45:41

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:27:33

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:26
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: PROPOFOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 08:30:20
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 Apr 2021 08:30:20
Data point term sent to Coder	System	15 Apr 2021 21:47:50
User entered 'Propofol'	(b) (4), (b) (6)	15 Apr 2021 21:47:05

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:27:33

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:26
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:22
User entered 'No (N)'	(b) (4), (b) (6)	15 Apr 2021 21:47:05

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 15:27:33**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:26
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:22
User entered 'General Anesthesia for left total hip arthroplasty'	(b) (4), (b) (6)	15 Apr 2021 21:47:05

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 15:27:33**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:26
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:22
User entered '150'	(b) (4), (b) (6)	15 Apr 2021 21:47:05

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:27:33

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:26
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:22
User entered 'mg (mg)'	(b) (4), (b) (6)	15 Apr 2021 21:47:05

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 15:27:33**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:26
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:22
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 21:47:05

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 15:27:33**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:26
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:22
User entered 'once (ONCE)'	(b) (4), (b) (6)	15 Apr 2021 21:47:05



US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:27:33

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:26
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:22
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 21:47:05

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 15:27:33**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:26
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:22
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	15 Apr 2021 21:47:05

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:27:33

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:26
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:22
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 21:47:05

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 15:27:33**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:26
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:22
User entered '08 Feb 2021'	(b) (4), (b) (6)	15 Apr 2021 21:47:05

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 15:27:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:26
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:22
User entered '0'	(b) (4), (b) (6)	15 Apr 2021 21:47:05

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 15:27:33**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:26
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:22
User entered 'No (N)'	(b) (4), (b) (6)	15 Apr 2021 21:47:05

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 15:27:33**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:26
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:22
User entered '08 Feb 2021'	(b) (4), (b) (6)	15 Apr 2021 21:47:05

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 15:27:33**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:26
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:22
User entered 'No (N)'	(b) (4), (b) (6)	15 Apr 2021 21:47:05



**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 15:27:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:26
User entered empty.	System	15 Apr 2021 21:47:05

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 15:27:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:26
User entered empty.	System	15 Apr 2021 21:47:05

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 15:27:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:26
User entered empty.	System	15 Apr 2021 21:47:05

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:27:33

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:19
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 01:41:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 01:41:09
Data point term sent to Coder	System	15 Apr 2021 21:49:00
User entered 'Fentanyl'	(b) (4), (b) (6)	15 Apr 2021 21:48:14

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 15:27:33**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:19
User entered 'No (N)'	(b) (4), (b) (6)	15 Apr 2021 21:48:14

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 15:27:33**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:19
User entered 'General Anesthesia for left total hip arthroplasty'	(b) (4), (b) (6)	15 Apr 2021 21:48:14

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 15:27:33**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:19
User entered '50'	(b) (4), (b) (6)	15 Apr 2021 21:48:14

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 15:27:33**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:19
User entered 'ug (ug)'	(b) (4), (b) (6)	15 Apr 2021 21:48:14



**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 15:27:33**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:19
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 21:48:14

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:27:33

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:19
User entered 'once (ONCE)'	(b) (4), (b) (6)	15 Apr 2021 21:48:14

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:27:33

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:19
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 21:48:14

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 15:27:33**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:19
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	15 Apr 2021 21:48:14

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:27:33

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:19
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 21:48:14

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 15:27:33**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:19
User entered '08 Feb 2021'	(b) (4), (b) (6)	15 Apr 2021 21:48:14

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 15:27:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:19
User entered '0'	(b) (4), (b) (6)	15 Apr 2021 21:48:14

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 15:27:33**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:19
User entered 'No (N)'	(b) (4), (b) (6)	15 Apr 2021 21:48:14



**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 15:27:33**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:19
User entered '08 Feb 2021'	(b) (4), (b) (6)	15 Apr 2021 21:48:14

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:27:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:19
User entered 'No (N)'	(b) (4), (b) (6)	15 Apr 2021 21:48:14

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 15:27:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:32
User entered empty.	System	15 Apr 2021 21:48:14

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 15:27:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:32
User entered empty.	System	15 Apr 2021 21:48:14

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 15:27:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:32
User entered empty.	System	15 Apr 2021 21:48:14

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:27:33

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:18
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: KETAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 02:01:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 02:01:18
Data point term sent to Coder	System	15 Apr 2021 21:50:04
User entered 'Ketamine'	(b) (4), (b) (6)	15 Apr 2021 21:49:06

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 15:27:33**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:18
User entered 'No (N)'	(b) (4), (b) (6)	15 Apr 2021 21:49:06

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 15:27:33**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:18
User entered 'General Anesthesia for left total hip arthroplasty'	(b) (4), (b) (6)	15 Apr 2021 21:49:06



**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 15:27:33**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:18
User entered '10'	(b) (4), (b) (6)	15 Apr 2021 21:49:06

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 15:27:33**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:18
User entered 'mg (mg)'	(b) (4), (b) (6)	15 Apr 2021 21:49:06

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 15:27:33**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:18
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 21:49:06

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 15:27:33**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:18
User entered 'once (ONCE)'	(b) (4), (b) (6)	15 Apr 2021 21:49:06

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:27:33

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:18
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 21:49:06

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 15:27:33**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:18
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	15 Apr 2021 21:49:06

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:27:33

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:18
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 21:49:06

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 15:27:33**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:18
User entered '08 Feb 2021'	(b) (4), (b) (6)	15 Apr 2021 21:49:06



US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:27:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:18
User entered '0'	(b) (4), (b) (6)	15 Apr 2021 21:49:06

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 15:27:33**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:18
User entered 'No (N)'	(b) (4), (b) (6)	15 Apr 2021 21:49:06

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:27:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:18
User entered '08 Feb 2021'	(b) (4), (b) (6)	15 Apr 2021 21:49:06

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 15:27:33**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:37:18
User entered 'No (N)'	(b) (4), (b) (6)	15 Apr 2021 21:49:06

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 15:27:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:38
User entered empty.	System	15 Apr 2021 21:49:06

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 15:27:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:38
User entered empty.	System	15 Apr 2021 21:49:06

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:27:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:38
User entered empty.	System	15 Apr 2021 21:49:06

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:27:33

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:36:55
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 14:46:48
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 Apr 2021 14:46:48
Data point term sent to Coder	System	15 Apr 2021 21:50:04
User entered 'Lidocaine'	(b) (4), (b) (6)	15 Apr 2021 21:49:59



**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 15:27:33**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:36:55
User entered 'No (N)'	(b) (4), (b) (6)	15 Apr 2021 21:49:59

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 15:27:33**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:36:55
User entered 'Regional Anesthesia for left total hip arthroplasty'	(b) (4), (b) (6)	15 Apr 2021 21:49:59

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 15:27:33**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:36:55
User entered '50'	(b) (4), (b) (6)	15 Apr 2021 21:49:59

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 15:27:33**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:36:55
User entered 'mg (mg)'	(b) (4), (b) (6)	15 Apr 2021 21:49:59

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 15:27:33**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:36:55
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 21:49:59

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:27:33

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System). DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	19 Apr 2021 14:29:50
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered with 'Start and stop dates are the same' (Site from System).	Judith Kirstein (b) (4) (b) (4)	15 Apr 2021 22:27:35
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	15 Apr 2021 21:49:59
User entered 'once (ONCE)'	(b) (4), (b) (6)	15 Apr 2021 21:49:59

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:27:33

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:36:55
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 21:49:59

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 15:27:33**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:36:55
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	15 Apr 2021 21:49:59



US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:27:33

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:36:55
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 21:49:59

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 15:27:33**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:36:55
User entered '08 Feb 2021'	(b) (4), (b) (6)	15 Apr 2021 21:49:59

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 15:27:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:36:55
User entered '0'	(b) (4), (b) (6)	15 Apr 2021 21:49:59

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 15:27:33**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:36:55
User entered 'No (N)'	(b) (4), (b) (6)	15 Apr 2021 21:49:59

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:27:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:36:55
User entered '08 Feb 2021' reason for change: New Information	(b) (4), (b) (6)	15 Apr 2021 22:32:45
User entered '08 Mar 2021'	(b) (4), (b) (6)	15 Apr 2021 21:49:59

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 15:27:33**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:36:55
User entered 'No (N)'	(b) (4), (b) (6)	15 Apr 2021 21:49:59

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 15:27:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:43
User entered empty.	System	15 Apr 2021 21:49:59

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 15:27:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:43
User entered empty.	System	15 Apr 2021 21:49:59



**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 15:27:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:43
User entered empty.	System	15 Apr 2021 21:49:59

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:27:33

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:36:03
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 12:43:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 12:43:45
Data point term sent to Coder	System	15 Apr 2021 21:52:06
User entered 'Zofran'	(b) (4), (b) (6)	15 Apr 2021 21:51:53

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:27:33

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:36:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Apr 2021 21:51:53

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 15:27:33**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:36:03
User entered 'Prevention of Nausea/Vomiting during left total hip arthroplasty'	(b) (4), (b) (6)	15 Apr 2021 21:51:53

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 15:27:33**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:36:03
User entered '4'	(b) (4), (b) (6)	15 Apr 2021 21:51:53

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:27:33

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:36:03
User entered 'mg (mg)'	(b) (4), (b) (6)	15 Apr 2021 21:51:53

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 15:27:33**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:36:03
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 21:51:53

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:27:33

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:36:03
User entered 'once (ONCE)'	(b) (4), (b) (6)	15 Apr 2021 21:51:53



US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:27:33

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:36:03
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 21:51:53

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 15:27:33**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:36:03
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	15 Apr 2021 21:51:53

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:27:33

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:36:03
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 21:51:53

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 15:27:33**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:36:03
User entered '08 Feb 2021'	(b) (4), (b) (6)	15 Apr 2021 21:51:53

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 15:27:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:36:03
User entered '0'	(b) (4), (b) (6)	15 Apr 2021 21:51:53

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 15:27:33**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:36:03
User entered 'No (N)'	(b) (4), (b) (6)	15 Apr 2021 21:51:53

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 15:27:33**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:36:03
User entered '08 Feb 2021'	(b) (4), (b) (6)	15 Apr 2021 21:51:53

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:27:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:36:03
User entered 'No (N)'	(b) (4), (b) (6)	15 Apr 2021 21:51:53



**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 15:27:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:49
User entered empty.	System	15 Apr 2021 21:51:53

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 15:27:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:49
User entered empty.	System	15 Apr 2021 21:51:53

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 15:27:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:49
User entered empty.	System	15 Apr 2021 21:51:53

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:27:33

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:55
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:36:02
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: DEXAMETHASONE, PRODUCTSYNONYM: DECADRON [DEXAMETHASONE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 09:28:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 09:28:54
Data point term sent to Coder	System	15 Apr 2021 21:53:09
User entered 'Decadron'	(b) (4), (b) (6)	15 Apr 2021 21:52:49

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 15:27:33**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:55
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:36:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Apr 2021 21:52:49

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 15:27:33**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:55
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:36:02
User entered 'Prevent inflammation from left total hip arthroplasty'	(b) (4), (b) (6)	15 Apr 2021 21:52:49

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 15:27:33**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:55
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:36:02
User entered '4'	(b) (4), (b) (6)	15 Apr 2021 21:52:49

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 15:27:33**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:55
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:36:02
User entered 'mg (mg)'	(b) (4), (b) (6)	15 Apr 2021 21:52:49



**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 15:27:33**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:55
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:36:02
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 21:52:49

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 15:27:33**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:55
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:36:02
User entered 'once (ONCE)'	(b) (4), (b) (6)	15 Apr 2021 21:52:49

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 15:27:33**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:55
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:36:02
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 21:52:49

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 15:27:33**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:55
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:36:02
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	15 Apr 2021 21:52:49

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 15:27:33**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:55
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:36:02
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 21:52:49

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 15:27:33**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:55
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:36:02
User entered '08 Feb 2021'	(b) (4), (b) (6)	15 Apr 2021 21:52:49

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 15:27:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:55
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:36:02
User entered '0'	(b) (4), (b) (6)	15 Apr 2021 21:52:49

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 15:27:33**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:55
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:36:02
User entered 'No (N)'	(b) (4), (b) (6)	15 Apr 2021 21:52:49



**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 15:27:33**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:55
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:36:02
User entered '08 Feb 2021'	(b) (4), (b) (6)	15 Apr 2021 21:52:49

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:27:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:55
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:36:02
User entered 'No (N)'	(b) (4), (b) (6)	15 Apr 2021 21:52:49

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 15:27:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:55
User entered empty.	System	15 Apr 2021 21:52:49

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 15:27:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:55
User entered empty.	System	15 Apr 2021 21:52:49

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 15:27:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:48:55
User entered empty.	System	15 Apr 2021 21:52:49

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:27:33

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:05
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:58
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS FOR SYSTEMIC USE, ATC: ALPHA- AND BETA-ADRENORECEPTOR AGONISTS, PRODUCT: EPHEDRINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 11:56:44
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 Apr 2021 11:56:44
Data point term sent to Coder	System	15 Apr 2021 21:54:10
User entered 'Ephedrine'	(b) (4), (b) (6)	15 Apr 2021 21:53:54

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:27:33

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:05
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Apr 2021 21:53:54

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 15:27:33**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:05
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:58
User entered 'Prevention of Bronchospasm during left total hip arthroplasty'	(b) (4), (b) (6)	15 Apr 2021 21:53:54



**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 15:27:33**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:05
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:58
User entered '40'	(b) (4), (b) (6)	15 Apr 2021 21:53:54

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:27:33

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:05
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:58
User entered 'mg (mg)'	(b) (4), (b) (6)	15 Apr 2021 21:53:54

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 15:27:33**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:05
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:58
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 21:53:54

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:27:33

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:05
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:58
User entered 'once (ONCE)'	(b) (4), (b) (6)	15 Apr 2021 21:53:54

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:27:33

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:05
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:58
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 21:53:54

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 15:27:33**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:05
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:58
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	15 Apr 2021 21:53:54

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 15:27:33**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:05
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:58
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 21:53:54

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 15:27:33**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:05
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:58
User entered '08 Feb 2021'	(b) (4), (b) (6)	15 Apr 2021 21:53:54



**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 15:27:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:05
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:58
User entered '0'	(b) (4), (b) (6)	15 Apr 2021 21:53:54

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 15:27:33**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:05
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:58
User entered 'No (N)'	(b) (4), (b) (6)	15 Apr 2021 21:53:54

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 15:27:33**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:05
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:58
User entered '08 Feb 2021'	(b) (4), (b) (6)	15 Apr 2021 21:53:54

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 15:27:33**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:05
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:58
User entered 'No (N)'	(b) (4), (b) (6)	15 Apr 2021 21:53:54

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 15:27:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:05
User entered empty.	System	15 Apr 2021 21:53:54

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 15:27:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:05
User entered empty.	System	15 Apr 2021 21:53:54

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 15:27:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:05
User entered empty.	System	15 Apr 2021 21:53:54

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:27:33

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:57
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES, ATC: ADRENERGIC AND DOPAMINERGIC AGENTS, PRODUCT: PHENYLEPHRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 09:25:43
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 Apr 2021 09:25:43
Data point term sent to Coder	System	15 Apr 2021 21:55:11
User entered 'Phenylephrine 0.75%'	(b) (4), (b) (6)	15 Apr 2021 21:55:08



US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:27:33

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Apr 2021 21:55:08

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 15:27:33**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:57
User entered 'Prevent intraoperative hypotension during left total hip arthroplasty'	(b) (4), (b) (6)	15 Apr 2021 21:55:08

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 15:27:33**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:57
User entered '500'	(b) (4), (b) (6)	15 Apr 2021 21:55:08

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:27:33

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:57
User entered 'mg (mg)'	(b) (4), (b) (6)	15 Apr 2021 21:55:08

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:27:33

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:57
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 21:55:08

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 15:27:33**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:57
User entered 'once (ONCE)'	(b) (4), (b) (6)	15 Apr 2021 21:55:08

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:27:33

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:57
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 21:55:08

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 15:27:33**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:57
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	15 Apr 2021 21:55:08



US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:27:33

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:57
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 21:55:08

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 15:27:33**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:57
User entered '08 Feb 2021'	(b) (4), (b) (6)	15 Apr 2021 21:55:08

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 15:27:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:57
User entered '0'	(b) (4), (b) (6)	15 Apr 2021 21:55:08

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 15:27:33**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:57
User entered 'No (N)'	(b) (4), (b) (6)	15 Apr 2021 21:55:08

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:27:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:57
User entered '08 Feb 2021'	(b) (4), (b) (6)	15 Apr 2021 21:55:08

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 15:27:33**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:09
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:57
User entered 'No (N)'	(b) (4), (b) (6)	15 Apr 2021 21:55:08

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 15:27:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:09
User entered empty.	System	15 Apr 2021 21:55:08

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 15:27:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:09
User entered empty.	System	15 Apr 2021 21:55:08



**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 15:27:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:09
User entered empty.	System	15 Apr 2021 21:55:08

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:27:33

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:54
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: BUPIVACAINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 01:11:10
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 Apr 2021 01:11:10
Data point term sent to Coder	System	15 Apr 2021 21:57:12
User entered 'Bupivacaine'	(b) (4), (b) (6)	15 Apr 2021 21:56:13

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 15:27:33**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:54
User entered 'No (N)'	(b) (4), (b) (6)	15 Apr 2021 21:56:13

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:27:33

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:54
User entered 'Local anesthesia for left total hip arthroplasty'	(b) (4), (b) (6)	15 Apr 2021 21:56:13

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 15:27:33**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:54
User entered '1.6'	(b) (4), (b) (6)	15 Apr 2021 21:56:13

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 15:27:33**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:54
User entered 'mL (mL)'	(b) (4), (b) (6)	15 Apr 2021 21:56:13

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:27:33

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:54
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 21:56:13

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 15:27:33**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:54
User entered 'once (ONCE)'	(b) (4), (b) (6)	15 Apr 2021 21:56:13



US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:27:33

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:54
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 21:56:13

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 15:27:33**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:54
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	15 Apr 2021 21:56:13

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 15:27:33**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:54
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 21:56:13

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:27:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:54
User entered '08 Feb 2021'	(b) (4), (b) (6)	15 Apr 2021 21:56:13

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 15:27:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:54
User entered '0'	(b) (4), (b) (6)	15 Apr 2021 21:56:13

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 15:27:33**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:54
User entered 'No (N)'	(b) (4), (b) (6)	15 Apr 2021 21:56:13

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:27:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:54
User entered '08 Feb 2021'	(b) (4), (b) (6)	15 Apr 2021 21:56:13

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:27:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:54
User entered 'No (N)'	(b)(4) (b)(6)	15 Apr 2021 21:56:13



**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 15:27:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:18
User entered empty.	System	15 Apr 2021 21:56:13

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 15:27:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:18
User entered empty.	System	15 Apr 2021 21:56:13

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 15:27:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:18
User entered empty.	System	15 Apr 2021 21:56:13

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:27:33

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:24
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:53
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE, PRODUCTSYNONYM: LACTATED RINGERS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 21:58:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Apr 2021 21:58:58
Data point term sent to Coder	System	15 Apr 2021 21:58:12
User entered 'Lactated Ringers'	(b) (4), (b) (6)	15 Apr 2021 21:57:41

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:27:33

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:24
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:53
User entered 'No (N)'	(b) (4), (b) (6)	15 Apr 2021 21:57:41

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 15:27:33**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:24
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:53
User entered 'Intraoperative hydration for left total hip arthroplasty'	(b) (4), (b) (6)	15 Apr 2021 21:57:41

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 15:27:33**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:24
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:53
User entered '1300'	(b) (4), (b) (6)	15 Apr 2021 21:57:41

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 15:27:33**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:24
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:53
User entered 'Other (OTHER)'	(b) (4), (b) (6)	15 Apr 2021 21:57:41



US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:27:33

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:24
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:53
User entered 'cc'	(b) (4), (b) (6)	15 Apr 2021 21:57:41

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:27:33

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:24
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:53
User entered 'once (ONCE)'	(b) (4), (b) (6)	15 Apr 2021 21:57:41

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 15:27:33**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:24
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:53
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 21:57:41

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 15:27:33**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:24
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:53
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	15 Apr 2021 21:57:41

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:27:33

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:24
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:53
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 21:57:41

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 15:27:33**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:24
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:53
User entered '08 Feb 2021'	(b) (4), (b) (6)	15 Apr 2021 21:57:41

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 15:27:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:24
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:53
User entered '0'	(b) (4), (b) (6)	15 Apr 2021 21:57:41

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 15:27:33**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:24
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:53
User entered 'No (N)'	(b) (4), (b) (6)	15 Apr 2021 21:57:41



US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:27:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:24
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:53
User entered '08 Feb 2021'	(b) (4), (b) (6)	15 Apr 2021 21:57:41

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:27:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:24
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:35:53
User entered 'No (N)'	(b) (4), (b) (6)	15 Apr 2021 21:57:41

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 15:27:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:24
User entered empty.	System	15 Apr 2021 21:57:41

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 15:27:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:24
User entered empty.	System	15 Apr 2021 21:57:41

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 15:27:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:49:24
User entered empty.	System	15 Apr 2021 21:57:41

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:27:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	03 May 2021 18:47:16
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.	Coder Import (b) (4) (b) (4)	03 May 2021 18:36:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 May 2021 18:36:22
Data point term sent to Coder	System	03 May 2021 18:35:15
User entered 'Tylenol'	(b) (4), (b) (6)	03 May 2021 18:35:04

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:27:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	03 May 2021 18:47:16
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 18:35:04

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:27:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	03 May 2021 18:47:16
User entered 'Pain from left hip replacement'	(b) (4), (b) (6)	03 May 2021 18:35:04



US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:27:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	03 May 2021 18:47:16
User entered '500'	(b) (4), (b) (6)	03 May 2021 18:35:04

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:27:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	03 May 2021 18:47:16
User entered 'mg (mg)'	(b) (4), (b) (6)	03 May 2021 18:35:04

US3162037

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 15:27:33**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	03 May 2021 18:47:16
User entered empty.	(b) (4), (b) (6)	03 May 2021 18:35:04

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:27:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	03 May 2021 18:47:16
User entered 'as needed (PRN)'	(b) (4), (b) (6) (b) (4)	03 May 2021 18:35:04

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:27:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	03 May 2021 18:47:16
User entered empty.	(b) (4), (b) (6)	03 May 2021 18:35:04

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:27:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	03 May 2021 18:47:16
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	03 May 2021 18:35:04

US3162037

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 15:27:33**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	03 May 2021 18:47:16
User entered empty.	(b) (4), (b) (6)	03 May 2021 18:35:04

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:27:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	03 May 2021 18:47:16
User entered '14 Apr 2021'	(b) (4), (b) (6)	03 May 2021 18:35:04



US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:27:33

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	03 May 2021 18:47:16
User entered '0'	(b) (4), (b) (6)	03 May 2021 18:35:04

US3162037

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:27:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	03 May 2021 18:47:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 May 2021 18:35:04

US3162037

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 15:27:33**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	03 May 2021 18:47:16
User entered empty.	(b) (4), (b) (6)	03 May 2021 18:35:04

US3162037

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 15:27:33**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	03 May 2021 18:47:16
User entered 'No (N)'	(b) (4), (b) (6)	03 May 2021 18:35:04

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 15:27:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 18:35:04

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 15:27:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 18:35:04

**US3162037**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 15:27:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 18:35:04

US3162037

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:27:33

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:03:18
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:09:59
User closed query 'Please add concomitant procedures (i.e. x-ray) associated with SAE to EDC. Thank you. ' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 23:09:45
Query 'Please add concomitant procedures (i.e. x-ray) associated with SAE to EDC. Thank you. ' answered with 'con procedure of x-ray has been added to con procedure log.' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 22:32:22
User opened query 'Please add concomitant procedures (i.e. x-ray) associated with SAE to EDC. Thank you. ' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 19:08:57
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:29:23
Signature has been broken.	Judith Kirstein (b) (4)	20 Feb 2021 18:32:07
User entered 'Yes (Y)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	20 Feb 2021 18:32:07
User signature succeeded.	Judith Kirstein (b) (4)	13 Feb 2021 01:34:22
User entered 'No (N)'	Jared Bradshaw (b) (4)	06 Aug 2020 21:08:57



**US3162037**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 09 Jun 2021 15:27:33**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:07:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:29:23
User entered '8 Feb 2021'	Judith Kirstein (b) (4) (b) (4)	20 Feb 2021 18:33:30

US3162037

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:27:33

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 23:22:39
DataPoint Un-verified.	(b) (4), (b) (6)	15 Apr 2021 21:35:19
Signature has been broken.	(b) (4), (b) (6)	15 Apr 2021 21:35:19
User entered 'LEFT HIP Arthroplasty' reason for change: New Information	(b) (4), (b) (6)	15 Apr 2021 21:35:19
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:07:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:29:23
User entered 'Left hip replacement'	Judith Kirstein (b) (4) (b) (4)	20 Feb 2021 18:33:30

US3162037

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:27:33

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:07:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:29:23
User entered 'Adverse Event (AE)'	Judith Kirstein (b) (4) (b) (4)	20 Feb 2021 18:33:30

US3162037

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:27:33

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:07:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:29:23
User entered empty.	Judith Kirstein (b) (4) (b) (4)	20 Feb 2021 18:33:30

US3162037

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:27:33

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:22:59
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:38:06
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	15 Apr 2021 21:40:17
User entered '13 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Apr 2021 21:40:17
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	15 Apr 2021 21:35:35
User entered '1 ' (non-conformant).	(b) (4), (b) (6)	15 Apr 2021 21:35:35

US3162037

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:27:33

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:22:59
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:38:06
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Apr 2021 21:40:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Apr 2021 21:40:17
User entered 'MRI of the left hip without contrast' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Apr 2021 21:40:17
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Apr 2021 21:35:35
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 21:35:35

US3162037

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:27:33

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:22:59
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:38:06
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Apr 2021 21:40:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Apr 2021 21:40:17
User entered 'Medical History (MH)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Apr 2021 21:40:17
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Apr 2021 21:35:35
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 21:35:35

US3162037

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:27:33

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:22:59
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:38:06
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 21:35:35



US3162037

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:27:33

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:23:02
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:38:04
User entered '08 Jan 2021'	(b) (4), (b) (6)	15 Apr 2021 21:40:42

US3162037

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:27:33

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:23:02
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:38:04
User entered 'Xray of pelvis and bilateral hips'	(b) (4), (b) (6)	15 Apr 2021 21:40:42

US3162037

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:27:33

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:23:02
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:38:04
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	15 Apr 2021 21:40:42

US3162037

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:27:33

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:23:02
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 23:38:04
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 21:40:42

**US3162037**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:27:33**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered 'USA-US074-2021-MRNA-1273-P301000012'	System	16 Feb 2021 23:02:38

**US3162037**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:27:33**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered 'Yes (Y)'	System	16 Feb 2021 23:02:38

US3162037

Folder: SAE USA-US074-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:33

Death

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered 'No (N)'	System	16 Feb 2021 23:02:38

US3162037

Folder: SAE USA-US074-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered 'No (N)'	System	16 Feb 2021 23:02:38



**US3162037**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:27:33**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered 'Yes (Y)'	System	16 Feb 2021 23:02:38

US3162037

Folder: SAE USA-US074-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered 'No (N)'	System	16 Feb 2021 23:02:38

US3162037

Folder: SAE USA-US074-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered 'No (N)'	System	16 Feb 2021 23:02:38

US3162037

Folder: SAE USA-US074-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered 'No (N)'	System	16 Feb 2021 23:02:38

US3162037

Folder: SAE USA-US074-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:33

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered 'Judith'	System	16 Feb 2021 23:02:38

US3162037

Folder: SAE USA-US074-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered 'Kirstein'	System	16 Feb 2021 23:02:38

US3162037

Folder: SAE USA-US074-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:33

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered '264 N HIGHLAND SPRINGS AVE, SUITE 4'	System	16 Feb 2021 23:02:38

US3162037

Folder: SAE USA-US074-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:33

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered 'BANNING'	System	16 Feb 2021 23:02:38



US3162037

Folder: SAE USA-US074-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:33

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered 'CA'	System	16 Feb 2021 23:02:38

**US3162037**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:27:33**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered '92220'	System	16 Feb 2021 23:02:38

US3162037

Folder: SAE USA-US074-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:33

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:11:23
User entered 'US'	System	16 Feb 2021 23:03:30

**US3162037**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:27:33**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	20 Apr 2021 13:28:52
User entered '3'	System	14 Apr 2021 15:06:54
User entered '2'	System	22 Feb 2021 17:11:40
User entered '1'	System	16 Feb 2021 23:03:30

**US3162037**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:27:33**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered 'USA-US074-2021-MRNA-1273-P301000012'	System	16 Feb 2021 23:02:38

**US3162037**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:27:33**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered 'Yes (Y)'	System	16 Feb 2021 23:02:38

US3162037

Folder: SAE USA-US074-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:33

Death

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered 'No (N)'	System	16 Feb 2021 23:02:38

US3162037

Folder: SAE USA-US074-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered 'No (N)'	System	16 Feb 2021 23:02:38



**US3162037**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:27:33**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered 'Yes (Y)'	System	16 Feb 2021 23:02:38

US3162037

Folder: SAE USA-US074-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered 'No (N)'	System	16 Feb 2021 23:02:38

US3162037

Folder: SAE USA-US074-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered 'No (N)'	System	16 Feb 2021 23:02:38

US3162037

Folder: SAE USA-US074-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered 'No (N)'	System	16 Feb 2021 23:02:38

US3162037

Folder: SAE USA-US074-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:33

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered 'Judith'	System	16 Feb 2021 23:02:38

US3162037

Folder: SAE USA-US074-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered 'Kirstein'	System	16 Feb 2021 23:02:38

**US3162037**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:27:33**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered '264 N HIGHLAND SPRINGS AVE, SUITE 4'	System	16 Feb 2021 23:02:38

US3162037

Folder: SAE USA-US074-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:33

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered 'BANNING'	System	16 Feb 2021 23:02:38



US3162037

Folder: SAE USA-US074-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:33

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered 'CA'	System	16 Feb 2021 23:02:38

US3162037

Folder: SAE USA-US074-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:33

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered '92220'	System	16 Feb 2021 23:02:38

US3162037

Folder: SAE USA-US074-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:33

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:11:23
User entered 'US'	System	16 Feb 2021 23:03:30

**US3162037**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:27:33**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	20 Apr 2021 13:28:52
User entered '3'	System	14 Apr 2021 15:06:54
User entered '2'	System	22 Feb 2021 17:11:40
User entered '1'	System	16 Feb 2021 23:03:30

**US3162037**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000012**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 15:27:33**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:39
User entered '16/Feb/2021 23:03'	System	16 Feb 2021 23:03:30

US3162037

Folder: SAE USA-US074-2021-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:27:33

**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.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:39
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:11:23
User entered 'I'	(b) (4), (b) (6)	16 Feb 2021 23:03:30

**US3162037**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:27:33**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered 'USA-US074-2021-MRNA-1273-P301000012'	System	16 Feb 2021 23:02:38

**US3162037**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:27:33**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered 'Yes (Y)'	System	16 Feb 2021 23:02:38



US3162037

Folder: SAE USA-US074-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:33

Death

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered 'No (N)'	System	16 Feb 2021 23:02:38

US3162037

Folder: SAE USA-US074-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered 'No (N)'	System	16 Feb 2021 23:02:38

**US3162037**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:27:33**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered 'Yes (Y)'	System	16 Feb 2021 23:02:38

US3162037

Folder: SAE USA-US074-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered 'No (N)'	System	16 Feb 2021 23:02:38

US3162037

Folder: SAE USA-US074-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered 'No (N)'	System	16 Feb 2021 23:02:38

US3162037

Folder: SAE USA-US074-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered 'No (N)'	System	16 Feb 2021 23:02:38

US3162037

Folder: SAE USA-US074-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:33

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered 'Judith'	System	16 Feb 2021 23:02:38

US3162037

Folder: SAE USA-US074-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered 'Kirstein'	System	16 Feb 2021 23:02:38



**US3162037**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:27:33**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered '264 N HIGHLAND SPRINGS AVE, SUITE 4'	System	16 Feb 2021 23:02:38

US3162037

Folder: SAE USA-US074-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:33

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered 'BANNING'	System	16 Feb 2021 23:02:38

US3162037

Folder: SAE USA-US074-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:33

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered 'CA'	System	16 Feb 2021 23:02:38

US3162037

Folder: SAE USA-US074-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:33

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered '92220'	System	16 Feb 2021 23:02:38

US3162037

Folder: SAE USA-US074-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:33

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:11:23
User entered 'US'	System	16 Feb 2021 23:03:30

**US3162037**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:27:33**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	20 Apr 2021 13:28:52
User entered '3'	System	14 Apr 2021 15:06:54
User entered '2'	System	22 Feb 2021 17:11:40
User entered '1'	System	16 Feb 2021 23:03:30

**US3162037**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000012**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 15:27:33**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
User entered '22/Feb/2021 12:11'	System	22 Feb 2021 17:11:40

US3162037

Folder: SAE USA-US074-2021-MRNA-1273-P301000012

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:27:33

**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.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 15:06:44
User entered 'I'	(b) (4), (b) (6)	22 Feb 2021 17:11:40



**US3162037**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:27:33**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered 'USA-US074-2021-MRNA-1273-P301000012'	System	16 Feb 2021 23:02:38

**US3162037**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:27:33**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered 'Yes (Y)'	System	16 Feb 2021 23:02:38

US3162037

Folder: SAE USA-US074-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:33

Death

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered 'No (N)'	System	16 Feb 2021 23:02:38

US3162037

Folder: SAE USA-US074-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered 'No (N)'	System	16 Feb 2021 23:02:38

**US3162037**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:27:33**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered 'Yes (Y)'	System	16 Feb 2021 23:02:38

US3162037

Folder: SAE USA-US074-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered 'No (N)'	System	16 Feb 2021 23:02:38

US3162037

Folder: SAE USA-US074-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered 'No (N)'	System	16 Feb 2021 23:02:38

US3162037

Folder: SAE USA-US074-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered 'No (N)'	System	16 Feb 2021 23:02:38



US3162037

Folder: SAE USA-US074-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:33

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered 'Judith'	System	16 Feb 2021 23:02:38

US3162037

Folder: SAE USA-US074-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered 'Kirstein'	System	16 Feb 2021 23:02:38

US3162037

Folder: SAE USA-US074-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:33

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered '264 N HIGHLAND SPRINGS AVE, SUITE 4'	System	16 Feb 2021 23:02:38

US3162037

Folder: SAE USA-US074-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:33

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered 'BANNING'	System	16 Feb 2021 23:02:38

**US3162037**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:27:33**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered 'CA'	System	16 Feb 2021 23:02:38

**US3162037**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:27:33**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered '92220'	System	16 Feb 2021 23:02:38

US3162037

Folder: SAE USA-US074-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:33

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:11:23
User entered 'US'	System	16 Feb 2021 23:03:30

**US3162037**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:27:33**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	20 Apr 2021 13:28:52
User entered '3'	System	14 Apr 2021 15:06:54
User entered '2'	System	22 Feb 2021 17:11:40
User entered '1'	System	16 Feb 2021 23:03:30



**US3162037**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000012**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 15:27:33**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:10
User entered '14/Apr/2021 11:06'	System	14 Apr 2021 15:06:54

US3162037

Folder: SAE USA-US074-2021-MRNA-1273-P301000012

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:27:33

**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.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 13:29:00
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:10
User entered 'I'	(b) (4), (b) (6)	14 Apr 2021 15:06:54

**US3162037**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:27:33**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered 'USA-US074-2021-MRNA-1273-P301000012'	System	16 Feb 2021 23:02:38

US3162037

Folder: SAE USA-US074-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:33

Serious

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered 'Yes (Y)'	System	16 Feb 2021 23:02:38

US3162037

Folder: SAE USA-US074-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:33

Death

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered 'No (N)'	System	16 Feb 2021 23:02:38

US3162037

Folder: SAE USA-US074-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered 'No (N)'	System	16 Feb 2021 23:02:38

**US3162037**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:27:33**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered 'Yes (Y)'	System	16 Feb 2021 23:02:38

US3162037

Folder: SAE USA-US074-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered 'No (N)'	System	16 Feb 2021 23:02:38



US3162037

Folder: SAE USA-US074-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered 'No (N)'	System	16 Feb 2021 23:02:38

US3162037

Folder: SAE USA-US074-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered 'No (N)'	System	16 Feb 2021 23:02:38

US3162037

Folder: SAE USA-US074-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:33

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered 'Judith'	System	16 Feb 2021 23:02:38

US3162037

Folder: SAE USA-US074-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered 'Kirstein'	System	16 Feb 2021 23:02:38

US3162037

Folder: SAE USA-US074-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:33

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered '264 N HIGHLAND SPRINGS AVE, SUITE 4'	System	16 Feb 2021 23:02:38

US3162037

Folder: SAE USA-US074-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:33

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered 'BANNING'	System	16 Feb 2021 23:02:38

**US3162037**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:27:33**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered 'CA'	System	16 Feb 2021 23:02:38

**US3162037**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:27:33**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 23:03:22
User entered '92220'	System	16 Feb 2021 23:02:38



US3162037

Folder: SAE USA-US074-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:27:33

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 19:00:42
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 17:11:23
User entered 'US'	System	16 Feb 2021 23:03:30

**US3162037**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:27:33**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	20 Apr 2021 13:28:52
User entered '3'	System	14 Apr 2021 15:06:54
User entered '2'	System	22 Feb 2021 17:11:40
User entered '1'	System	16 Feb 2021 23:03:30

**US3162037**

**Folder: SAE USA-US074-2021-MRNA-1273-P301000012**

**Form: Safety Report Form (4)**

**Generated On: 09 Jun 2021 15:27:33**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 22:50:13
	(b) (4)	
User entered '20/Apr/2021 09:28'	System	20 Apr 2021 13:28:52

US3162037

Folder: SAE USA-US074-2021-MRNA-1273-P301000012

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:27:33

**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.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 22:50:13
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 13:29:00
User entered 'I'	(b) (4), (b) (6)	20 Apr 2021 13:28:52